

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF DELAWARE

3  
4 UNITED THERAPEUTICS CORPORATION,)  
5 Plaintiff, )  
6 v. ) C.A. No. 23-975-RGA  
7 LIQUIDIA TECHNOLOGIES, INC., )  
8 Defendant. )

9  
10 J. Caleb Boggs Courthouse  
11 844 North King Street  
12 Wilmington, Delaware

13  
14 Monday, September 30, 2024  
15 9:02 a.m.  
16 Markman Hearing

17  
18 BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

19 APPEARANCES:

20  
21 MORRIS NICHOLS ARSHT & TUNNELL LLP  
22 BY: MICHAEL J. FLYNN, ESQUIRE

23  
24 -and-

25 GOODWIN LAW FIRM  
26 BY: WILLIAM JACKSON, ESQUIRE  
27 BY: ERIC ROMEO, ESQUIRE

28  
29 -and-

30  
31 McDERMOTT WILL & EMERY  
32 BY: ART DYKHUIS, ESQUIRE  
33 BY: DOUGLAS H. CARSTEN, ESQUIRE  
34 BY: ADAM W. BURROWBRIDGE, ESQUIRE  
35 BY: JAKE B. VALLEN, ESQUIRE

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37 For the Plaintiff

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1 APPEARANCES CONTINUED:

2 SHAW KELLER LLP  
3 BY: KAREN E. KELLER, ESQUIRE

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5 COOLEY LLP  
6 BY: SANYA SUKDUANG, ESQUIRE  
7 BY: JONATHAN DAVIES, ESQUIRE  
8 BY: JOHN HABIBI, ESQUIRE  
9 BY: RACHEL PRESTON, ESQUIRE  
10 BY: ROSALYND UPTON, ESQUIRE

08:49:23 8 For the Defendant

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08:49:23 9

09:02:22 10 \*\*\* PROCEEDINGS \*\*\*

09:02:22 11 DEPUTY CLERK: All rise.

09:02:30 12 THE COURT: All right. Good morning, everyone.

09:02:33 13 So we've got a Markman in *United Therapeutics*

09:02:37 14 *vs. Liquidia*, which is Civil Action Number 23-975. Everyone

09:02:41 15 can be seated.

09:02:42 16 Mr. Flynn.

09:02:43 17 MR. FLYNN: Good morning, Your Honor. Michael

09:02:48 18 Flynn from Morris Nichols on behalf of United Therapeutics.

09:02:51 19 At counsel table is William Jackson and Eric Romeo from

09:02:55 20 Goodwin. Art Dykhuis and Adam Burrowbridge from McDermott.

09:02:58 21 And in the back we have Doug Carsten and Jake Vallen of

09:02:58 22 McDermott Will & Emery.

09:03:03 23 Mr. Dykhuis, I believe, will do the first term  
09:03:06 24 today.

09:03:07 25 THE COURT: All right. Ms. Keller.

09:03:10 1 MS. KELLER: Good morning, Your Honor. Karen  
09:03:14 2 Keller from Shaw Keller on behalf of the Defendant. With me  
09:03:16 3 today, Sanya Sukduang, Jonathan Davies and Rosalynd Upton,  
09:03:21 4 all from Cooley. Also, Rachel Preston and John Habibi from  
09:03:25 5 Cooley. And Russ Schundler from Liquidia.

09:03:28 6 THE COURT: All right. Well, good morning to  
09:03:29 7 everyone.

09:03:31 8 So we've got three terms. Before we start, can  
09:03:35 9 someone just tell me where we are generally?

09:03:40 10 And by that, I mean, I denied a preliminary  
09:03:46 11 injunction some time ago, but as I recall or right about the  
09:03:49 12 same time that I denied it or afterwards, something  
09:03:53 13 happened. Maybe the FDA did something that means that the  
09:03:59 14 Defendant is not likely to be launching real soon.

09:04:06 15 Can someone tell me about that?

09:04:08 16 MR. SUKDUANG: Yes, Your Honor. So I think  
09:04:11 17 there are two FDA things going on. So when you denied your  
09:04:14 18 PI motion, UTC had simultaneously brought an action, an APA  
09:04:20 19 action in the District of Delaware.

09:04:22 20 THE COURT: District of Columbia?

09:04:23 21 MR. SUKDUANG: Yeah, District of Columbia also  
09:04:25 22 seeking a PI. The District of Columbia denied that PI.  
09:04:29 23 Then recently, I believe in August or early September of  
09:04:33 24 this year, the FDA granted United Therapeutics additional  
09:04:43 25 exclusivity for their dry powder which will run until May of

09:04:48 1 2025.

09:04:49 2 THE COURT: Oh, okay.

09:04:50 3 MR. SUKDUANG: And so because of that, Liquidia

09:04:54 4 cannot launch their product until at least May of 2025.

09:05:00 5 Based on that, Liquidia filed its own APA action in the

09:05:03 6 District of Columbia. Summary judgment briefing on the

09:05:09 7 propriety of the exclusivity is being briefed and summary

09:05:14 8 judgment argument will be in December of 2024.

09:05:18 9 THE COURT: And you say "the propriety," is it  
09:05:21 10 the case that Liquidia's saying it should be longer or it's  
09:05:24 11 the case that United Therapeutics is saying it shouldn't be,  
09:05:28 12 I guess, at all?

09:05:29 13 MR. SUKDUANG: No, so flipped. So Liquidia is  
09:05:31 14 saying there should be no exclusivity granted to UTC so it  
09:05:35 15 should be able to launch.

09:05:36 16 THE COURT: Oh.

09:05:37 17 MR. SUKDUANG: And UTC and the FDA is trying to  
09:05:39 18 defend that position. So depending on the outcome of  
09:05:42 19 summary judgment, in December, before the District of  
09:05:47 20 Columbia, UTC -- Liquidia may be able to launch before May  
09:05:50 21 or we may be stuck until May.

09:05:52 22 THE COURT: All right. But, in any event, the  
09:05:58 23 way things are kind of teed up right now, the District Court  
09:06:03 24 in the District of Columbia who's basically the agent who's  
09:06:07 25 going to -- agent is not the right word, but the judge

09:06:11 1 that's going to decide something that, if necessary, or, you  
09:06:15 2 know, if there needs to be immediate action, it's going to  
09:06:18 3 be because of something the judge there does --

09:06:20 4 MR. SUKDUANG: Yes.

09:06:21 5 THE COURT: -- at least up until May of 2025.

09:06:23 6 MR. SUKDUANG: Up until May of 2025. And  
09:06:26 7 whether UTC tries to renew, I don't think the factors have  
09:06:29 8 changed. But, again, we'll have to wait until December.

09:06:32 9 THE COURT: Okay. All right.

09:06:33 10 Thank you. All right.

09:06:34 11 So we've got these three terms. I assume we're  
09:06:38 12 going to do them in the same order they show up in the  
09:06:40 13 briefing?

09:06:42 14 MR. DYKHUIS: Yes, Your Honor.

09:06:46 15 THE COURT: And first off, remind me who you  
09:06:48 16 are.

09:06:49 17 MR. DYKHUIS: Art Dykhuis with McDermott.

09:06:54 18 THE COURT: All right. So I was curious in  
09:06:57 19 terms of the first term here, in the Plaintiff's proposed  
09:07:13 20 construction, you say, to the extent it needs to be  
09:07:17 21 construed, it is "one or more, unless context clearly  
09:07:21 22 dictates otherwise."

09:07:23 23 Where in the claims does the context clearly  
09:07:26 24 dictate otherwise?

09:07:28 25 MR. DYKHUIS: Where -- well, Your Honor, there's

09:07:31 1 a few different places. And the --

09:07:35 2 MR. JACKSON: May I?

09:07:36 3 MR. DYKHUIS: Your Honor, may we approach with  
09:07:38 4 some slides?

09:07:40 5 THE COURT: Oh, yeah. Sure.

09:07:47 6 MR. DYKHUIS: So there's a few -- I'll directly  
09:07:49 7 answer the Court's question. There is a couple examples  
09:07:51 8 that come to mind when you asked where does context dictate  
09:07:54 9 otherwise. And if we could actually have Slide 4.

09:08:00 10 This is Claim 1. "A" and "the" shows up  
09:08:04 11 throughout Claim 1 and throughout the dependent claims 50,  
09:08:08 12 60 instances. Just in Claim 1, you have in the parties'  
09:08:13 13 briefing, it addresses a patient. So by administration to  
09:08:16 14 the patient having pulmonary hypertension -- excuse me. A  
09:08:20 15 patient and then the patient. So if the scope -- if an  
09:08:25 16 embodiment is being mapped to the claims in some way for  
09:08:27 17 infringement or invalidity, and it's pointing at a single  
09:08:31 18 patient, then the patient would have to match that. So the  
09:08:33 19 context would dictate if you're looking at -- if you're  
09:08:37 20 evaluating one patient, the patient would refer back to that  
09:08:39 21 one patient.

09:08:41 22 Another example would be a maximum tolerated  
09:08:44 23 dose. In context it seems to make sense that a patient  
09:08:47 24 would have a one maximum tolerated dose versus some plural  
09:08:50 25 set of maximum tolerated doses.

09:08:52 1 THE COURT: So I'm not sure. What I understand  
09:08:55 2 you're saying is let's just talk about "a" or "and" first.

09:09:02 3 MR. DYKHUIS: Okay.

09:09:02 4 THE COURT: Is there any place where "a" or  
09:09:04 5 "and" does not mean one or more?

09:09:06 6 MR. DYKHUIS: The one example I just gave, Your  
09:09:12 7 Honor, maximum tolerated dose, I think there it would be one  
09:09:14 8 that the patient would have a maximum tolerated dose.  
09:09:17 9 Another example would be that Claim 1 itself is a method and  
09:09:20 10 it's defining the outer bounds of a method.

09:09:23 11 Those are the two examples that come to mind,  
09:09:25 12 Your Honor. And the point --

09:09:27 13 THE COURT: All right. Well, so is it -- it  
09:09:30 14 says -- I forget how many claims there are, but I think  
09:09:33 15 there's something like --

09:09:33 16 MR. DYKHUIS: Sixteen.

09:09:34 17 THE COURT: -- 19?

09:09:35 18 MR. DYKHUIS: I believe 16.

09:09:36 19 THE COURT: How many?

09:09:39 20 MR. DYKHUIS: I've got a copy of the patent  
09:09:41 21 right here.

09:09:42 22 THE COURT: So do I.

09:09:43 23 MR. DYKHUIS: Nineteen.

09:09:44 24 THE COURT: Yes. Are all 19 asserted?

09:09:46 25 MR. DYKHUIS: I think all except for Claim 13,

09:09:48 1 Your Honor.

09:09:48 2 THE COURT: Okay. Not a nebulizer.

09:09:52 3 All right. Well, when we're through today, I  
09:09:58 4 would like you to point out to me -- I would like you-all to  
09:10:06 5 write a letter that basically identifies in the 18 asserted  
09:10:11 6 claims every place where "a" does not mean one or more.

09:10:18 7 All right?

09:10:18 8 MR. DYKHUIS: We can do that, Your Honor.

09:10:20 9 THE COURT: Okay. And then whatever -- all  
09:10:29 10 right.

09:10:30 11 In terms of the -- do you agree that the  
09:10:34 12 patent -- there's an attempt at lexicography here?

09:10:40 13 MR. DYKHUIS: That is right. I think you're  
09:10:42 14 thinking of Column 6.

09:10:44 15 THE COURT: Right. And when I say "an attempt  
09:10:48 16 at lexicography," there is lexicography. Maybe there's a  
09:10:53 17 question about how good lexicography it is, but definitely  
09:10:58 18 the patentee's, when we're talking about "a" and "the" are  
09:11:02 19 attempting to be lexicographers; right?

09:11:05 20 MR. DYKHUIS: I believe so. That's right, Your  
09:11:07 21 Honor.

09:11:07 22 THE COURT: Okay. The phrase "includes plural  
09:11:10 23 referents, unless the context clearly dictates otherwise,"  
09:11:14 24 let's skip the "unless the context clearly dictates  
09:11:18 25 otherwise." "Includes plural referents," is that just a

09:11:27 1 strange patent lawyer way of saying one or more?

09:11:30 2 MR. DYKHUIS: Yes, Your Honor.

09:11:31 3 THE COURT: Okay. All right.

09:11:33 4 Well, I don't think right now I need to -- so  
09:11:38 5 actually let me just go -- I've got one other question for  
09:11:41 6 you, I think.

09:11:42 7 So what does Claim 2 -- where it says, "The  
09:11:53 8 method of Claim 1, wherein said administering provides a  
09:11:56 9 statistically significant increase of a six-minute walk  
09:12:00 10 distance in the patient after 8 weeks, 12 weeks or  
09:12:03 11 16 weeks," I take it the after 8 weeks, 12 weeks or 16 weeks  
09:12:09 12 means any one of the three will do?

09:12:13 13 MR. DYKHUIS: Yes, Your Honor.

09:12:14 14 THE COURT: Okay. So what does -- providing "a  
09:12:20 15 statistically significant increase of a six-minute walk  
09:12:24 16 distance," how do you determine that?

09:12:29 17 MR. DYKHUIS: Your Honor, I believe you -- well,  
09:12:34 18 you look at the data for the method that's being used. And  
09:12:39 19 what we have in the patent is it describes individual  
09:12:42 20 patients being treated, of course, but also clinical studies  
09:12:44 21 that were conducted. Specifically looking at this  
09:12:47 22 indication, the PH-ILD indication and following the regimen  
09:12:51 23 that's in Claim 1.

09:12:52 24 And so what you can look at for Claim 2 and what  
09:12:55 25 we did at the PI stage is analyze: What data do we have?

09:13:01 1 And you can look back at the data that's in the patent, for  
09:13:04 2 example, and it describes statistically significant results  
09:13:07 3 at those time points.

09:13:08 4 THE COURT: So I haven't gone back to look at  
09:13:10 5 the patent for that, but in Claim 3, it talks about an  
09:13:13 6 increase of what I believe is 20 meters. 10M, whatever M  
09:13:17 7 is --

09:13:18 8 MR. DYKHUIS: Right.

09:13:19 9 THE COURT: -- after eight weeks. So does that  
09:13:22 10 mean that if you do this method with a patient and that  
09:13:26 11 particular patient can walk 11 meters after eight weeks, it  
09:13:30 12 falls within the claim? But if the patient can only walk  
09:13:33 13 nine meters, it doesn't, all other things being equal?

09:13:38 14 MR. DYKHUIS: All other things being equal?

09:13:42 15 THE COURT: In other words, don't argue with me  
09:13:43 16 about, well, 12 weeks, 16 weeks.

09:13:46 17 MR. DYKHUIS: Oh, sure.

09:13:47 18 THE COURT: Sorry.

09:13:47 19 MR. DYKHUIS: What I would say, Your Honor, is  
09:13:51 20 if there are -- I'm searching for the right table. It's  
09:13:55 21 Table 5 or 6, but, in essence, there's data in the patent  
09:13:59 22 that reflects the statistically significant results. And  
09:14:02 23 the average results in different forms of data for the  
09:14:05 24 patients that were in the study that was conducted and  
09:14:08 25 described in the specification.

09:14:09 1                   And really when Claim 2 and these other claims  
09:14:13 2 are referring back, they reference the administering in the  
09:14:16 3 method of Claim 1. And so the question is: For a given --  
09:14:20 4 obviously, candidly, Liquidia is, of course, intending to  
09:14:25 5 sell their product to one patient or multiple patients. And  
09:14:27 6 when those patients follow the method that's in Claim 1,  
09:14:30 7 that would be infringing.

09:14:31 8                   And necessarily we would have to ask: What do  
09:14:33 9 we know about the method that, for example, Liquidia will be  
09:14:37 10 using? We know the characteristics of that method are that  
09:14:40 11 it will provide a statistically significant increase after  
09:14:43 12 six -- of a six-minute walk distance. It will provide an  
09:14:46 13 increase of --

09:14:47 14                   THE COURT: Well --

09:14:48 15                   MR. DYKHUIS: -- for the average patient.

09:14:50 16                   THE COURT: -- let's say we know that because of  
09:14:52 17 what you've got in the rest of the patent. How does proving  
09:14:55 18 Claim 2 differ from proving Claim 1?

09:14:58 19                   MR. DYKHUIS: I'm not sure if I understand the  
09:15:05 20 Court's question.

09:15:06 21                   THE COURT: Well, okay. So there's a narrowing  
09:15:10 22 because it's a dependent claim. What part of -- what in  
09:15:16 23 Claim 1 is now not part of Claim 2?

09:15:19 24                   MR. DYKHUIS: It -- well, I'm going to state the  
09:15:24 25 obvious, but I'm not trying to be dense about this. So as

09:15:30 1 you mentioned, Your Honor, the -- Claim 2 does narrow. It  
09:15:33 2 could be -- it's not the case here. It could be that  
09:15:35 3 somebody develops a different drug and they do their own  
09:15:39 4 clinical studies. It may be those clinical studies show  
09:15:43 5 that actually their product, for whatever reason, is  
09:15:44 6 ineffective. It doesn't provide a statistically significant  
09:15:47 7 increase. Maybe there's no statistical significance or  
09:15:50 8 there was no improvement numerically whatsoever --

09:15:53 9 THE COURT: So --

09:15:54 10 MR. DYKHUIS: -- that --

09:15:54 11 THE COURT: -- Claim 2 is essentially adding in  
09:15:59 12 it has passed FDA, I don't know, standards for getting a  
09:16:03 13 drug?

09:16:04 14 MR. DYKHUIS: I don't see FDA specifically  
09:16:07 15 there, but certainly it would require statistical  
09:16:09 16 significance which implicates, of course, a clinical study  
09:16:12 17 of some sort.

09:16:13 18 THE COURT: But does Claim 2 require that you  
09:16:16 19 prove -- basically your reading of Claim 2 is it means sort  
09:16:22 20 of Claim 1, and there's a clinical study that shows Claim 1  
09:16:31 21 will do claim -- the add-on of Claim 2?

09:16:35 22 MR. DYKHUIS: If I -- yes. Yes, Your Honor.  
09:16:38 23 That's my understanding.

09:16:39 24 THE COURT: Okay. And, roughly speaking, Claims  
09:16:44 25 2 and 3 sort of parallel each other except that, I guess, 10

09:16:50 1       meters is a rounded-off number from whatever is  
09:16:54 2       statistically significant. But how do Claims 2 and 3 differ  
09:16:59 3       from each other?

09:17:01 4                   MR. DYKHUIS: Just in terms of I think their  
09:17:06 5       words, Your Honor. I don't know. I'd have to page back  
09:17:09 6       through the patent and find out how it's statistically  
09:17:12 7       significant.

09:17:12 8                   THE COURT: But is Claims 2 and 3 -- I guess  
09:17:18 9       what I'm wondering is: Does Claim 3 depend on what happens  
09:17:22 10      to the particular patient to whom the method is  
09:17:25 11      administered, but Claim 2 does not?

09:17:29 12                   MR. DYKHUIS: It -- Claim 2 -- I think the  
09:17:34 13       answer to that is, yes, Your Honor. The Claim 2 recites the  
09:17:36 14       statistical significant increase. And I think we can look  
09:17:40 15       at a study for that. And that's how it was addressed at the  
09:17:42 16       PI stage.

09:17:43 17                   Claim 3, excuse me, I think you can do one of  
09:17:47 18       two ways. You could look at the patient. Did they get that  
09:17:53 19       increase?

09:17:53 20                   But you could also look at the clinical trial  
09:17:56 21       data and see: What do we know about the product that's  
09:17:59 22       being administered according to this method?

09:18:01 23                   THE COURT: So you administer the method to a  
09:18:05 24       patient. And instead of increasing how much they can walk,  
09:18:10 25       they don't. But you're saying that still meets Claim 3

09:18:16 1 because you can prove it by statistics?

09:18:19 2 MR. DYKHUIS: Certainly for Claim 2, it does. I  
09:18:21 3 think that would be an option for Claim 3, yes, because what  
09:18:25 4 we're looking at, the patent is describing a clinical study  
09:18:28 5 and data. And it's claiming a method of treatment. And  
09:18:32 6 clinical studies always reflect this, Your Honor, that not  
09:18:36 7 every single patient necessarily will get exactly the same  
09:18:39 8 benefit. And so certainly patients, for one reason or  
09:18:43 9 another, will have varying degrees in success from the  
09:18:46 10 treatment.

09:18:46 11 THE COURT: But Claim 3, I think, claims that  
09:18:49 12 the patient does get this benefit, not some other guy out  
09:18:53 13 there who was part of a clinical trial. It's talking about  
09:18:56 14 the patient who got the treatment, isn't it?

09:19:00 15 MR. DYKHUIS: This is another time where I just  
09:19:04 16 have to apologize, Your Honor. I'm not sure I followed that  
09:19:06 17 question.

09:19:07 18 THE COURT: Okay. Well, so it says, "The method  
09:19:11 19 of Claim 1 wherein," blah, blah, blah, the patient increases  
09:19:19 20 the walk distance by the recited amount.

09:19:22 21 MR. DYKHUIS: Right.

09:19:23 22 THE COURT: You're saying that you could be  
09:19:25 23 treating a patient who doesn't increase by the recited  
09:19:30 24 amount, and yet they still meet the limitations because some  
09:19:35 25 other people in the clinical trial did meet the recited

09:19:39 1 amount?

09:19:41 2 MR. DYKHUIS: What the -- I'm trying to make,  
09:19:43 3 Your Honor, and I'm answering the question as directly as I  
09:19:46 4 can. The point is some -- these claims have no requirement  
09:19:50 5 that after the method is performed that a doctor perform  
09:19:55 6 measurements.

09:19:55 7 THE COURT: I didn't say -- I mean, yeah. Okay.

09:20:00 8 MR. DYKHUIS: And if I may, so the point there  
09:20:03 9 is there's no requirement to go out and measure individual  
09:20:06 10 patients each time. We can still analyze infringement  
09:20:10 11 because we're able to look at, Okay, what are the  
09:20:12 12 characteristics and the output from a clinical study which  
09:20:16 13 we know has been conducted and reflects the results of the  
09:20:21 14 method that's claimed in Claim 1?

09:20:22 15 And in this instance, Your Honor, we know that  
09:20:25 16 Liquidia, for example, is relying on UTC's clinical data to  
09:20:29 17 support its own application. So, in essence, the results  
09:20:33 18 that we have at issue here that show statistical  
09:20:36 19 significance, that show increases in six-minute walk  
09:20:38 20 distance is the very same data that describes Liquidia's  
09:20:43 21 products, at least as it represents to the FDA.

09:20:45 22 THE COURT: So if the -- let's assume, for the  
09:20:52 23 sake of argument, the statistically significant increase in  
09:20:55 24 your clinical trials was 10 meters. If that were the case,  
09:21:00 25 then Claims 2 and 3 would be exactly the same?

09:21:05 1 MR. DYKHUIS: I don't read Claim 2 and Claim 3  
09:21:14 2 as exactly the same.

09:21:15 3 THE COURT: Well, so listen to my hypothetical.  
09:21:18 4 How would it be different if the statistically significant  
09:21:20 5 increase was 10 meters?

09:21:23 6 MR. DYKHUIS: Well, number one, Your Honor,  
09:21:27 7 it -- the statistical significance is a limitation in and of  
09:21:33 8 itself. So within Claim 3, if there's no statistical  
09:21:37 9 significance in whatever data that is being analyzed, you  
09:21:41 10 could point to data that didn't show statistical  
09:21:44 11 significance, I believe, for three, but not for two. At  
09:21:47 12 least the statistical significance as an explicit limitation  
09:21:50 13 in two.

09:21:51 14 And just to put it in context. Claim 1 is a  
09:21:54 15 method of improving exercise capacity. So that's a  
09:21:57 16 broader -- Claim 2 is the specific increase in six-minute  
09:22:02 17 walk distance. But it's a statistically significant  
09:22:05 18 increase, whereas in Claim 3 it's an increase in that  
09:22:09 19 specific measure of exercise capacity, six-minute walk  
09:22:12 20 distance. And it puts a specific number on it, 10 meters,  
09:22:15 21 and could be -- depending on the data you're looking at, the  
09:22:18 22 10 meters is the statistically significant number or it  
09:22:21 23 could be a different number.

09:22:22 24 THE COURT: Right. No. I understand that that  
09:22:25 25 is -- that's the reason I was asking. You assume that it

09:22:26 1 was the statistically significant number.

09:22:32 2 Okay. All right. Let me hear from the other  
09:22:34 3 side.

09:22:34 4 MR. DYKHUIS: Thank you, Your Honor.

09:22:36 5 THE COURT: Thank you.

09:22:37 6 MR. SUKDUANG: Your Honor, I think

09:22:37 7 Mr. Dykhuis --

09:22:51 8 MR. DAVIES: Your Honor, may I approach with  
09:22:52 9 binders?

09:22:53 10 THE COURT: Sure. Yes.

09:22:54 11 MR. SUKDUANG: I'm sorry. I think Mr. Dykhuis'  
09:22:59 12 attempted explanation to your questions evidences the  
09:23:02 13 problems with the claim. Claim 1 requires an improvement in  
09:23:10 14 exercise capacity. Claim 2 -- so that could be done with a  
09:23:15 15 single patient.

09:23:17 16 Claim 2 depends from Claim 1 and requires a  
09:23:21 17 statistical significant change. You cannot do that with a  
09:23:24 18 single patient. And what UTC is trying to do is use written  
09:23:28 19 description support, which is a validity issue, and  
09:23:31 20 enablement, and use that to say a single patient by Liquidia  
09:23:35 21 will prove infringement.

09:23:36 22 You can't -- our label doesn't do that. It  
09:23:39 23 doesn't instruct taking the "data," as UTC just  
09:23:43 24 acknowledged, and extrapolate its statistical significance.  
09:23:47 25 So Claim 2 requires multiple patients collecting the data

09:23:53 1 and determining whether there's statistical significance.

09:23:57 2 Claim 3 doesn't depend from Claim 1. It doesn't

09:24:01 3 depend from Claim 2. It depends from Claim 1.

09:24:04 4 Claim 3 says if you look at the patient in Claim

09:24:07 5 1 and you're improving exercise capacity, by what measure do

09:24:12 6 I assess that? Claim 3 says you look at six-minute walk and

09:24:17 7 you improve it by 10 meters.

09:24:19 8 So the difference between the claims goes back

09:24:21 9 to the optional language that UTC is trying to include with

09:24:25 10 the or. They want to establish infringement of the

09:24:30 11 statistically significant claims by pointing to a single

09:24:35 12 patient by Liquidia.

09:24:36 13 But then for invalidity, they're going to

09:24:39 14 require Liquidia to prove that a single patient is not

09:24:45 15 enough. And we've seen that already in the PI context. In

09:24:49 16 the PI context, Liquidia -- UTC argued, and it's their

09:24:54 17 declarant, Dr. Nathan, DI-28 at Paragraphs 209 and 211. It

09:24:59 18 says you need a clinical trial to prove invalidity

09:25:04 19 reasonable expectation of success.

09:25:05 20 They argued -- UTC argued itself, DI-26 -- this

09:25:08 21 is their opening PI brief at Pages 12 to 13 -- that you need

09:25:12 22 a clinical trial to prove invalidity reasonable expectation

09:25:17 23 of success. If that's the case for the statistical

09:25:20 24 significant claims, then that has to be the construction for

09:25:25 25 infringement because you cannot construe Claim 2 permitting

09:25:30 1 infringement by a single patient and then requiring for  
09:25:34 2 invalidity Liquidia to prove multiple patients. And that is  
09:25:39 3 the fundamental problem that we see with the "one or more."

09:25:43 4 On the issue of "one or more," most of the cases  
09:25:48 5 or actually all of the cases that UTC cites, including the  
09:25:51 6 *Azurity* case, the Defendant, like Liquidia, tries to limit  
09:25:56 7 "a" to a single buffer, a single person, a single something,  
09:26:00 8 not more than a single. We're not trying to do that. We're  
09:26:04 9 actually trying to give meaning to "a," and "the" and "and"  
09:26:07 10 when you look at Claim 1, and you look at Claim 2 and you  
09:26:10 11 look at all the statistical significant claims which require  
09:26:14 12 more.

09:26:14 13 You asked Mr. Dykhuis: How do you figure out  
09:26:20 14 the statistical significant part of Claim 2? And the  
09:26:25 15 specification tells you that. I'm at Slide 8 of our slides,  
09:26:28 16 but it's Column 31.

09:26:30 17 UTC argued in their reply brief that Claim 2 can  
09:26:34 18 be proven by a single patient, that you don't need multiple  
09:26:38 19 patients to prove a statistical significance. That's wrong.  
09:26:42 20 The specification teaches you at Slide -- Page 31 that in  
09:26:46 21 order to determine, in order to provide written description  
09:26:50 22 and enablement support for those claims, the study had to  
09:26:55 23 have -- had to be powered sufficiently enough to run a  
09:26:58 24 statistical analysis. And for the six-minute walk test,  
09:27:02 25 they used a mixed model measurement. That's a statistical

09:27:06 1 analysis.

09:27:06 2 You cannot infringe with a single patient. When  
09:27:10 3 you look at the dependent claims, the secondary endpoints  
09:27:14 4 like NT-proBNP of FDC, the specification tells you that if  
09:27:19 5 the primary endpoint is met, which is six-minute walk, you  
09:27:23 6 have to -- you can look at the secondary endpoints, these  
09:27:26 7 dependent claims. And they, too, used a statistical  
09:27:30 8 analysis, the hierachal testing procedure.

09:27:32 9 Our fundamental issue and the reason why we  
09:27:37 10 believe our construction is correct, and I understand the  
09:27:40 11 proclivity with "one or more," is that the specification  
09:27:46 12 specifically says "includes," "includes plural" "unless the  
09:27:53 13 context dictates otherwise."

09:27:55 14 What UTC is trying to do is take "the context  
09:27:57 15 dictates otherwise" and make that the rule when that is the  
09:28:01 16 exception. The exception is the "or." And there is nothing  
09:28:05 17 in the specification that UTC points to that calls it  
09:28:09 18 optionally. The lexicography that they used doesn't use  
09:28:13 19 optional language. And when you look at the claims as a  
09:28:16 20 whole and trying to construe these claims consistently  
09:28:20 21 between Claim 1 and Claim 2, and I'm at Slide 7 here, the  
09:28:25 22 "or" -- "and more" is required for the statistical  
09:28:31 23 significance, not the "or."

09:28:33 24 And what UTC is going to do, and again, we've  
09:28:37 25 seen it already and Mr. Dykhuis just confirmed it today,

09:28:39 1 they want to take a single patient that Liquidia may treat  
09:28:45 2 or a doctor may treat and say because that single patient  
09:28:49 3 may fall into what a clinical trial was done under control  
09:28:53 4 conditions years earlier, you automatically infringe.

09:28:56 5 That is not the case. The issue is whether our  
09:29:00 6 label -- and these are all method claims -- whether our  
09:29:01 7 label instructs, induces, suggests to doctors to treat  
09:29:08 8 someone with inhaled treprostinil so that individuals get a  
09:29:14 9 statistically significant change. We do not do that.

09:29:20 10 They're trying to avoid that outcome by pointing  
09:29:23 11 to the "or" optional language. Our construction comports  
09:29:27 12 with the claims as a whole and the express language in the  
09:29:31 13 specification about include, not optionally.

09:29:35 14 So I've tried to address those issues. You  
09:29:39 15 probably have questions for me, maybe not. The "unless" --  
09:29:44 16 or "unless the context dictates otherwise," we don't think  
09:29:48 17 that should be a part of the construction because that's the  
09:29:50 18 exception, not the rule.

09:29:51 19 UTC wants to make it the rule. And there's  
09:29:54 20 nothing in the claims that dictates otherwise.

09:29:57 21 THE COURT: All right. Thank you.

09:30:00 22 Okay. Well, I'm done.

09:30:10 23 MR. SUKDUANG: Oh, okay. I thought you had  
09:30:12 24 something else.

09:30:12 25 THE COURT: No. That's okay.

09:30:18 1 All right. Well, so we've got lexicography  
09:30:20 2 here, and it says the singular forms and -- and "the include  
09:30:27 3 plural referents, unless the context clearly dictates  
09:30:30 4 otherwise." I take that to be, as I said, lexicography.  
09:30:36 5 And I take it that the way of saying one or more, "unless  
09:30:50 6 the context clearly dictates otherwise."

09:30:53 7 So I am going to construe it as being one or  
09:30:56 8 more. But I think the "unless the context dictates  
09:31:01 9 otherwise" leaves too much wiggle room in for the Plaintiff,  
09:31:10 10 which is the reason why I want a letter where they say for  
09:31:19 11 "a," "and," and "the," where the context clearly dictates  
09:31:24 12 otherwise, and when they have that, what the otherwise is.  
09:31:31 13 Presumably from context, it's that it's singular.

09:31:38 14 And so I don't understand this to be, you  
09:31:42 15 know -- so the claims, they've got to be construed one way  
09:31:48 16 or the other. You know, how that applies to invalidity,  
09:31:52 17 infringement, that's an issue for another day.

09:31:55 18 So maybe by the end of this week, Mr. Dykhuis,  
09:32:03 19 you can submit a letter that for every claim other than 13  
09:32:10 20 states what it is. So that at the end of the day, the  
09:32:14 21 construction will not be "one or more unless the context  
09:32:19 22 dictates otherwise" because we'll know which ones the  
09:32:23 23 context dictates otherwise. So it will be fixed.

09:32:26 24 Okay?

09:32:26 25 MR. DYKHUIS: Understood. Thank you.

09:32:28 1 THE COURT: All right.

09:32:29 2 MR. SUKDUANG: Your Honor, just a clarification.

09:32:32 3 Do you want both parties to submit by the end of the week or

09:32:35 4 just UTC? And do we get to respond?

09:32:37 5 THE COURT: Well, if they submit something and

09:32:39 6 you want to respond, that's fine. You know, I just want

09:32:42 7 to -- and it may be that -- but I would like to know what

09:32:47 8 their view is. And so in the context or in the -- with the

09:32:53 9 understanding that basically it is one or more, you know,

09:33:00 10 you can indicate, after they've done it, where you think

09:33:03 11 the -- where they have indicated the context wrongly. Okay?

09:33:07 12 And maybe I'll address that now or maybe I'll address that

09:33:12 13 somewhere down the road.

09:33:13 14 All right. So let's go on to "maximum tolerated

09:33:16 15 dose."

09:33:18 16 And actually, given the fact that this is an

09:33:27 17 indefiniteness argument, why don't I hear from the Defendant

09:33:30 18 first.

09:33:32 19 MR. BURROWBRIDGE: Yes, Your Honor.

09:33:38 20 THE COURT: So my first question, because I will

09:33:41 21 have some questions for you is: Don't you think any medical

09:33:48 22 professional understands the concept of "maximum tolerated

09:33:51 23 dose"? Isn't that something that is, I don't know, well

09:33:56 24 understood in the medical field?

09:33:58 25 MR. SUKDUANG: I think in the abstract, yes,

09:34:01 1 Your Honor. But when you look at the claims, the claims are  
09:34:03 2 written in a particular way here. So --

09:34:06 3 THE COURT: So let's just follow that in the  
09:34:09 4 abstract. Would you say "maximum tolerated dose" is  
09:34:13 5 essentially a term of art in the medical field that doctors,  
09:34:21 6 persons of ordinary skill in the art would understand?

09:34:23 7 MR. SUKDUANG: I think we can agree that in the  
09:34:26 8 abstract outside this patent, a "maximum tolerated dose"  
09:34:30 9 could be understood by a doctor.

09:34:32 10 THE COURT: Okay. And would you say it's a term  
09:34:36 11 of art or is it not even that complex? Because --

09:34:40 12 MR. SUKDUANG: I'm not sure it's a term of art  
09:34:42 13 because I'm not sure doctors use "maximum tolerated dose."  
09:34:47 14 I think when you look at labels, it just says titrate up or  
09:34:51 15 it tells you what the maximum dose is, like you can only go  
09:34:55 16 to 400 milligrams or whatever it might be. But I agree with  
09:35:01 17 your original premise.

09:35:03 18 THE COURT: Okay. All right.

09:35:04 19 So with that being the case, you have some  
09:35:08 20 burden here to show that they've deviated from that meaning.  
09:35:14 21 And so why don't you go ahead and try to persuade me.

09:35:18 22 MR. SUKDUANG: Sure. I understand and we  
09:35:19 23 understand that the burden on us is clear and convincing.  
09:35:22 24 It's an invalidity argument with indefiniteness.

09:35:24 25 Outside the context, as we talked about, a

09:35:26 1 doctor might understand that a patient might understand  
09:35:28 2 that, but you have to look at "maximum tolerated dose" in  
09:35:31 3 the context of these claims.

09:35:33 4 Claim 1 requires improving exercise capacity.  
09:35:38 5 That is one outcome for treatment. Okay. Claim 2, Claim 5,  
09:35:45 6 Claim 6, Claim 9 depend directly from Claim 1. They require  
09:35:50 7 a different outcome measure.

09:35:52 8 Claim 5 is a good example. NT-proBNP, right.  
09:35:57 9 So Claim 5 depends from Claim 1. In order to meet -- fall  
09:36:02 10 within the scope of Claim 5, the patient has to first have  
09:36:06 11 improved exercise capacity. And then, in addition to  
09:36:11 12 improved exercise capacity, they have to have a reduction in  
09:36:17 13 NT-proBNP. That means from baseline that value has to look  
09:36:21 14 negative or decreased. Two separate, distinct measured  
09:36:26 15 outcomes based on a "maximum tolerated dose."

09:36:29 16 The problem with the specification, the problem  
09:36:32 17 with the claims and why it's indefinite is because there is  
09:36:37 18 no clarity or certainty within the specification as to  
09:36:41 19 which -- if I don't meet one, which outcome dictates  
09:36:46 20 "maximum tolerated dose."

09:36:48 21 And I want to go to the examples, Table 5.  
09:36:53 22 Well, first, when you look at the specification, the maximum  
09:36:56 23 dose that patients were given is 72 micrograms at week 16.

09:37:00 24 Okay. When you look at Table 5, all of the  
09:37:03 25 patients at week 16 had improved six-minute walk. That is

09:37:08 1 the improved exercise capacity of Claim 1.

09:37:12 2 Okay. But at that same time point, 16 weeks,  
09:37:17 3 when you look at that second measurement, NT-proBNP, and  
09:37:21 4 that's Claim 5, some patients improved. That's the negative  
09:37:25 5 number.

09:37:26 6 But other patients, their NT-proBNP got worse.

09:37:30 7 That's the positive, 5, 3, 7, 3. Right.

09:37:34 8 So you're supposed to see from baseline. If  
09:37:36 9 you're improving, if you're meeting Claim 5, it should be  
09:37:40 10 less than what you were at baseline, the negative numbers.

09:37:43 11 If you're worsening, you're getting the positive numbers and  
09:37:47 12 that's what we've outlined in the red box.

09:37:49 13 The conflict and the indefiniteness comes from  
09:37:52 14 this exact outcome. If I meet Claim 1 at 72 micrograms, and  
09:37:59 15 I have improved exercise capacity, that same patient has  
09:38:06 16 worsening NT-proBNP at that same dose. Which outcome  
09:38:11 17 measured dictates the "maximum tolerated dose"? The  
09:38:15 18 specification does not tell you that.

09:38:18 19 And there's two different ways within Claim 5 to  
09:38:23 20 assess "maximum tolerated dose." Do I look at exercise  
09:38:28 21 capacity, because I have to meet that for Claim 1, or do I  
09:38:32 22 look at NT-proBNP, because that's a requirement from Claim  
09:38:36 23 5? A doctor, a patient, a skilled artisan does not have  
09:38:43 24 reasonable certainty, based on the specification itself, as  
09:38:48 25 to which measurement I use.

09:38:50 1                   And that's like the Teva case. That was  
09:38:52 2 molecular weight, and you can measure molecular weight three  
09:38:55 3 different ways.

09:38:56 4                   That is analogous to what the specification of  
09:38:58 5 the '327 teaches. It can measure outcomes based on  
09:39:02 6 administration and the "maximum tolerated dose" in multiple  
09:39:06 7 different ways.

09:39:06 8                   And if I go back to the claims, you can look at  
09:39:09 9 exercise capacity for Claim 1. All of the dependent claims  
09:39:14 10 require exercise capacity. Claim 2, you can look at it as a  
09:39:18 11 six-minute walk test. Claim 5, you can look at it  
09:39:20 12 separately as NT-proBNP. Claim 6, you can look at an  
09:39:24 13 exacerbation of interstitial lung disease. Or Claim 9, an  
09:39:29 14 improvement in FEC.

09:39:31 15                   These are not the same outcomes. They are not  
09:39:34 16 the same measurements. And there is no indication that if I  
09:39:38 17 hit the "maximum tolerated dose" for Claim 1 that I'm going  
09:39:43 18 to improve any of these dependent claims with that "maximum  
09:39:48 19 tolerated dose."

09:39:48 20                   And if I have to increase the "maximum tolerated  
09:39:52 21 dose" to meet this NT-proBNP, then I might fail the exercise  
09:39:57 22 capacity. That patient might withdraw.

09:40:00 23                   When you look at the definition of "maximum  
09:40:02 24 tolerated dose," there is none in the specification. But  
09:40:06 25 it's used twice. Once when discussing therapeutically

09:40:10 1 effective, and therapeutic effective is disease progression  
09:40:15 2 onset, delaying onset of symptoms. "Maximum tolerated dose"  
09:40:19 3 is also addressed in functional improvement like the  
09:40:22 4 six-minute walk test.

09:40:23 5 Those two issues don't align. How do we see  
09:40:26 6 that? Again, the specification tells you that they are  
09:40:30 7 different outcome measures that lead to different results  
09:40:33 8 based on the same dose.

09:40:35 9 Figure 4 is the six-minute walk again at weeks  
09:40:38 10 4, 8, 12 and 16. Claim 1, you get that improvement. You  
09:40:42 11 don't need statistical significance in Claim 1.

09:40:45 12 Figure 2, people discontinued treprostинil  
09:40:49 13 therapy because of disease progression. How do those two  
09:40:53 14 align? Whether you're looking at a functional improvement,  
09:40:56 15 which is one usage of "maximum tolerated dose" versus  
09:41:00 16 disease progression, there is another use of "maximum  
09:41:05 17 tolerated dose." That is the lack of certainty within the  
09:41:08 18 claims.

09:41:08 19 Again, when you're looking at "maximum tolerated  
09:41:15 20 dose," if the specification or the claims were written as  
09:41:24 21 independent claims, each of them independent, we wouldn't  
09:41:27 22 have this argument because you could just look at exercise  
09:41:31 23 capacity. Yes. Or you can look at NT-proBNP by itself,  
09:41:34 24 independent of exercise capacity. Yes.

09:41:37 25 The problem comes from how the claims are

09:41:40 1 written where they all depend from Claim 1. And when you  
09:41:44 2 look at the dependent claims, two independent and unrelated  
09:41:50 3 outcomes need to be achieved. And the specification teaches  
09:41:53 4 you that with the maximum dose, you don't necessarily get  
09:41:58 5 that double outcome with the doses given.

09:42:01 6 That is the basis for invalidity. That is the  
09:42:05 7 basis for indefiniteness.

09:42:06 8 I won't cover, unless you want me to, our  
09:42:10 9 alternative construction, but that is our basis.

09:42:12 10 THE COURT: So doesn't "maximum tolerated dose"  
09:42:21 11 refer to the amount that the patient is given, not relative  
09:42:31 12 to outcomes that it's designed to be treating for, but you  
09:42:41 13 know, essentially when side effects or, you know, it starts  
09:42:48 14 to have some negative consequences for the patient?

09:42:52 15 MR. SUKDUANG: No, not within the claims because  
09:42:54 16 the claims -- it's a method claim. You have to treat this  
09:42:57 17 patient.

09:43:00 18 THE COURT: So let's assume the "maximum  
09:43:01 19 tolerated dose" before the patient overdoses is 10 grams or  
09:43:07 20 10 micrograms. If it improves lung capacity or exercise  
09:43:14 21 capacity, you've proved that prong. If you also prove  
09:43:22 22 reduction of NT-proBNP, then you've proved a dependent  
09:43:27 23 claim.

09:43:27 24 If you don't prove the reduction of NT-proBNP,  
09:43:32 25 well then you haven't proved the dependent claim, but you

09:43:36 1 still proved the independent claim. And, of course, if you  
09:43:39 2 don't improve exercise capacity, then you haven't proved  
09:43:42 3 anything. I mean, you don't meet any claims.

09:43:44 4 MR. SUKDUANG: Right, right. But the issue is  
09:43:46 5 you have to have a max -- the claim requires a "maximum  
09:43:49 6 tolerated dose." So you have to -- you have -- the way the  
09:43:53 7 specification reads, and we heard this with respect to "a"  
09:43:59 8 and "the," the studies done in the patent were not, Let's  
09:44:05 9 just dose the people until we see an improvement. The  
09:44:09 10 specification and the examples were, Let's give them the  
09:44:13 11 maximum dose and assess the various improvements.

09:44:18 12 And so you have to go through. And the way this  
09:44:21 13 disease works, it's a progressive disease. Patients are  
09:44:27 14 going to have to take more and more of the drug over time  
09:44:30 15 because their disease is going to get worse and worse and  
09:44:33 16 worse. That's the therapeutically effective part. You want  
09:44:36 17 to delay disease progression.

09:44:38 18 So a patient starts on at 50 micrograms and  
09:44:41 19 feels good. Then you start seeing things gets worse. You  
09:44:44 20 increase the dose and you see things getting worse and  
09:44:46 21 increase the dose.

09:44:48 22 At some point that patient may have improved  
09:44:52 23 exercise capacity, but no NT-proBNP improvement. Or vice  
09:44:57 24 versa, you start seeing improvement in one of these other  
09:44:59 25 functions, but then they can't tolerate the drug.

09:45:04 1 And so that's the lack of certainty. Where do I  
09:45:09 2 go when I look at what is required by the claims; right?  
09:45:16 3 Again, I come back to the issue of infringement and  
09:45:20 4 validity. UTC is going to say you need to prove all these  
09:45:23 5 things --

09:45:23 6 THE COURT: All right. You know, I've heard  
09:45:25 7 enough. I don't think it's indefiniteness. You know, I  
09:45:27 8 think "maximum tolerated dose" is essentially independent of  
09:45:33 9 whether the thing works or not. And it's going to be the  
09:45:38 10 same for one patient. It's going to be the same no matter  
09:45:42 11 what measurement of improved, you know, exercise capacity or  
09:45:51 12 reduction is in NT-proBNP you're talking about.

09:45:58 13 So I'm not going to find that this is indefinite  
09:46:02 14 by clear and convincing evidence. And I don't actually  
09:46:07 15 think it needs to be construed.

09:46:12 16 All right?

09:46:12 17 MR. SUKDUANG: Okay. Thank you, Your Honor.

09:46:13 18 THE COURT: All right. Is there anything  
09:46:15 19 Plaintiff wants to say?

09:46:18 20 MR. DYKHUIS: No, Your Honor. Thank you.

09:46:20 21 THE COURT: All right. Let's go on to "pulsed  
09:46:26 22 inhalation device."

09:46:30 23 All right. You're Mr. Carsten; right?

09:46:31 24 MR. JACKSON: I'm Mr. Jackson. Thank you. I'm  
09:46:34 25 honored to be confused with Mr. Carsten, but I'm

09:46:37 1 Mr. Jackson.

09:46:37 2 THE COURT: Okay. Sorry about that.

09:46:39 3 MR. JACKSON: All good. Thank you.

09:46:41 4 So may it please the Court. Here's the -- here  
09:46:47 5 are the two parties' constructions.

09:46:49 6 THE COURT: Right.

09:46:50 7 MR. JACKSON: Our construction is "device that  
09:46:52 8 provides for non-continuous inhaled drug delivery." Theirs  
09:46:56 9 is "a device that provides the force for non-continuous drug  
09:47:00 10 delivery." So it's literally the same except the words "the  
09:47:03 11 force."

09:47:04 12 So the ultimate question here is: Where does  
09:47:08 13 the force have to come from? Any pulse -- you've got a  
09:47:12 14 pulse in your veins right now. Your heart's doing that. A  
09:47:17 15 wave is a pulse of water. There are lots of things that are  
09:47:19 16 pulses. There has to be some force to create that pulse.  
09:47:23 17 It could be wind, gravity, a difference in pressure,  
09:47:27 18 whatever, but there has to be something that creates a  
09:47:30 19 pulse.

09:47:30 20 Their construction requires that pulse to come  
09:47:32 21 only from the device. That is an incorrect construction  
09:47:37 22 on -- this is a sort of summary of where we're going, but  
09:47:39 23 let me walk you through.

09:47:40 24 These are the claims. "Pulsed inhalation  
09:47:44 25 device," and it says 14 is -- "a pulse inhalation device is

09:47:48 1 a dry powder inhaler."

09:47:49 2 THE COURT: And excuse me a second, Mr. Jackson.

09:47:53 3 So the "pulsed inhalation device" has nothing to do with

09:47:57 4 Claims 1 to 10; right?

09:48:01 5 MR. JACKSON: With the exception of 1 -- 11  
09:48:04 6 depends on 1.

09:48:07 7 THE COURT: Right. But, I mean, 1 to 10,  
09:48:12 8 there's no -- this dispute is irrelevant to Claims 1  
09:48:18 9 through 10; right?

09:48:18 10 MR. JACKSON: Correct. Correct.

09:48:19 11 THE COURT: Okay. But then does it apply to all  
09:48:26 12 the rest of the claims?

09:48:27 13 MR. JACKSON: Again, with the exception of 13  
09:48:29 14 which --

09:48:29 15 THE COURT: Right, because that's out of the  
09:48:31 16 case.

09:48:31 17 MR. JACKSON: Can I have the patent?

09:48:33 18 MR. DYKHUIS: Yeah.

09:48:38 19 THE COURT: So I'm guessing it doesn't really  
09:48:40 20 apply to Claims 15 and on. All it really applies to is  
09:48:51 21 Claims 11, 12 and 14; right?

09:48:52 22 MR. JACKSON: Correct, Your Honor.

09:48:53 23 THE COURT: Okay. Thank you.

09:48:54 24 MR. JACKSON: Yeah. So we know that the "pulsed  
09:48:56 25 inhalation device" is a dry powder inhaler. So let's look

09:49:01 1 at what the specification says about "pulsed inhalation  
09:49:03 2 device" and dry powder inhalers.

09:49:05 3 THE COURT: Wait. Hold on a minute.

09:49:08 4 So in Claim 14, it's a dry powder inhaler, but  
09:49:13 5 it's not a dry powder -- it's not limited to a dry powder  
09:49:18 6 inhaler in Claims 11 and 12.

09:49:21 7 MR. JACKSON: Correct, Your Honor.

09:49:23 8 THE COURT: Okay. So, I'm sorry. Go ahead.

09:49:36 9 MR. JACKSON: Yeah. So we know that the "pulsed  
09:49:41 10 inhalation device" includes dry powder inhalers. Right.  
09:49:45 11 Claim 14 says "the pulsed inhalation device."

09:49:47 12 THE COURT: It can certainly include some dry  
09:49:50 13 powder inhalers.

09:49:51 14 MR. JACKSON: Sure. Not all. Not all.

09:49:52 15 THE COURT: Right.

09:49:53 16 MR. JACKSON: It doesn't have to be all. All  
09:49:54 17 I'm asking for is some dry powder inhalers.

09:49:57 18 THE COURT: Yes.

09:49:58 19 MR. JACKSON: So let's look at what the  
09:50:00 20 specification says. So this is at Column 21, Lines 6  
09:50:03 21 through 14. The first line says, "The inhalation device,  
09:50:05 22 such as a pulsed inhalation device, may be a dry powder  
09:50:07 23 inhaler." Again, so we know that the pulsed inhalation  
09:50:11 24 device may be a dry powder inhaler.

09:50:14 25 In that same paragraph, at the bottom of the

09:50:17 1 paragraph, it says, "For example, a dry powder inhaler and  
09:50:20 2 dry powder composition or formulation can be found in  
09:50:26 3 *Guarneri*." That's what that reference is.

09:50:28 4 THE COURT: Okay.

09:50:28 5 MR. JACKSON: So let's see what *Guarneri* says.  
09:50:31 6 This is *Guarneri*. *Guarneri* is a -- involves a dry powder  
09:50:35 7 inhaler that is a breath-powered inhaler. So the force  
09:50:39 8 comes from the breath.

09:50:41 9 When you're -- when the question about whether  
09:50:43 10 the force -- the way the force has to come from, this  
09:50:46 11 answers that question. *Guarneri* says the -- which is  
09:50:49 12 referenced again and incorporated into the patent -- the dry  
09:50:53 13 powder inhaler is a breath-powered inhaler.

09:50:58 14 THE COURT: And a dry powder inhaler, is that  
09:51:13 15 basically just referring to the fact that it's using dry  
09:51:19 16 powder as opposed to a gas, or a liquid or something else?

09:51:25 17 MR. JACKSON: Yes, yes. So you can breathe in a  
09:51:27 18 mist. You can breathe in -- lots of kids have asthma, and  
09:51:31 19 they have that little meter-dosed inhaler. You squeeze it  
09:51:34 20 and it shoots a little mist into your mouth.

09:51:36 21 THE COURT: Right. The thing you're talking  
09:51:38 22 about where you squeeze it, that is that force; right?

09:51:41 23 MR. JACKSON: That has its own force, and it's  
09:51:43 24 compressed air, right, that you squeeze.

09:51:45 25 THE COURT: Right.

09:51:45 1 MR. JACKSON: Correct.

09:51:46 2 THE COURT: Right.

09:51:46 3 MR. JACKSON: So that's an example that has the  
09:51:48 4 power inside it. Correct.

09:51:49 5 THE COURT: Right. But getting to a dry powder  
09:51:51 6 inhaler, what that would involve is very fine granules of  
09:51:56 7 something?

09:51:56 8 MR. JACKSON: Correct.

09:51:57 9 THE COURT: And so a dry powder inhaler could be  
09:52:02 10 something where you have a device that supplies the force or  
09:52:06 11 it could be something where, for example, breaths of the  
09:52:10 12 human supplies the force?

09:52:11 13 MR. JACKSON: Correct, Your Honor.

09:52:12 14 THE COURT: And are there other options?

09:52:15 15 MR. JACKSON: I can -- I think, since you've got  
09:52:17 16 a device and you've got a device and a -- it's either  
09:52:20 17 supplied by the device or by the human. Like I don't know  
09:52:23 18 any other options.

09:52:24 19 THE COURT: Okay. All right.

09:52:26 20 MR. JACKSON: No. I think -- it's a good  
09:52:28 21 question. I like it totally. And there are --

09:52:31 22 THE COURT: You like totally random questions?

09:52:34 23 MR. JACKSON: Well, I would have been trying to  
09:52:36 24 think through like the differences that -- there's  
09:52:39 25 continuous and there's pulsed. Those are the two

09:52:42 1 distinctions, right.

09:52:43 2 The continuous is like the cannula that people  
09:52:46 3 have for the oxygen over there and then through their nose,  
09:52:48 4 and they're continuously breathing. Or you've got a  
09:52:51 5 respirator that you're continuously breathing through.

09:52:54 6 THE COURT: Okay.

09:52:54 7 MR. JACKSON: Right. That's a continuous or  
09:52:56 8 it's pulsed. It's delivered in pulses like a wave. Like  
09:52:58 9 a --

09:52:58 10 THE COURT: And does pulsed refer to, you know,  
09:53:04 11 you do it as needed, or you do it every two hours or that  
09:53:08 12 kind of thing as opposed to --

09:53:11 13 MR. JACKSON: Yes, Your Honor, constant  
09:53:14 14 infusion.

09:53:14 15 THE COURT: Like with the forced one that you  
09:53:16 16 squeeze one, wait a second, squeeze another?

09:53:19 17 MR. JACKSON: Well, each of those would be a  
09:53:21 18 pulse. It's the continuous. It's -- the distinction is  
09:53:24 19 between pulsed and continuous, right.

09:53:26 20 So a continuous is you're always on it. It's  
09:53:28 21 like those cannulas.

09:53:29 22 THE COURT: So the cannula, would that be  
09:53:31 23 pulsed?

09:53:31 24 MR. JACKSON: No, that's continuous. You're  
09:53:33 25 just breathing it in through your nose and it's continually

09:53:36 1 driving.

09:53:36 2 THE COURT: So pulsed is --

09:53:38 3 MR. JACKSON: Pulsed is like a bolus of -- like

09:53:39 4 you're taking a shot of something. Like it's a pulse of --

09:53:45 5 THE COURT: Right.

09:53:46 6 MR. JACKSON: -- the medication.

09:53:46 7 THE COURT: Right. So, and that got to -- I

09:53:48 8 think this was in the briefing some -- pulsed essentially

09:53:52 9 means non-continuous. That's the reason why both sides have

09:53:56 10 non-continuous in their construction.

09:53:59 11 MR. JACKSON: Yes, Your Honor. All right.

09:54:02 12 So, again, *Guarneri*, a cite referenced in the

09:54:05 13 patent as an example of a dry powder inhaler. And we know

09:54:10 14 *Guarneri* is breath-powered. So we know that the force does

09:54:12 15 not come from the device, it comes from the person.

09:54:15 16 THE COURT: And so *Guarneri*, that's actually  
09:54:17 17 prior art to this?

09:54:18 18 MR. JACKSON: Yes.

09:54:18 19 THE COURT: Okay. And I guess in a way it makes  
09:54:28 20 sense that if you have fine enough grains of whatever it is  
09:54:32 21 you're inhaling, that you can -- that a person could just  
09:54:41 22 breathe it in and get it far enough up their nose or  
09:54:44 23 possibly mouth.

09:54:48 24 Inhaler, does that mean through the nose?

09:54:50 25 MR. JACKSON: I think it means through the

09:54:51 1 mouth. I think it's inhaled. I mean, I guess it could be,  
09:54:55 2 in theory, through the nose. The example that everybody's  
09:54:59 3 talking about, all the examples here are through the mouth  
09:55:02 4 into the lungs. It's being pulled down into the lungs.

09:55:04 5 THE COURT: Okay. All right. Okay.

09:55:08 6 MR. JACKSON: And, again, the focus of the  
09:55:10 7 difference is whether the device has to perform the force.

09:55:14 8 THE COURT: Right. And so I think in the  
09:55:15 9 briefing, and you can help me out here by going through  
09:55:17 10 these things, besides for *Guarneri*, there were other places  
09:55:20 11 where you said the embodiments describe or there's reference  
09:55:28 12 that shows it covers dry powder inhalers; right?

09:55:32 13 MR. JACKSON: Yes. So my next example is  
09:55:36 14 also -- this is also in the patent. "Inhaled compositions  
09:55:39 15 may include dry powder compositions." And then on the  
09:55:43 16 bottom line it says -- it has a reference. It discloses  
09:55:46 17 "which are incorporated by reference." That's for *Roscigno*.

09:55:50 18 Here is *Roscigno*. That is, again, it allows the  
09:55:54 19 cap -- that's a device that you squeeze. It allows the  
09:55:57 20 capsule to spin -- the centrifugal force drives the powder  
09:56:03 21 out and then you breathe it in. So that's another example  
09:56:05 22 of a breath-powered, inhaled, pulsed --

09:56:10 23 THE COURT: Well, the "centrifugal force," does  
09:56:16 24 that help -- I mean, is that a force -- is the device  
09:56:27 25 there -- isn't the device there providing some of the force?

09:56:30 1 MR. JACKSON: So the device pierces the little  
09:56:34 2 capsule and then spins it to pull the powder out of the  
09:56:38 3 capsule. But it's still in your -- it's at the other end of  
09:56:42 4 the pipes where those two little pipes are, right.

09:56:44 5 THE COURT: Okay.

09:56:45 6 MR. JACKSON: And you have to suck it in so  
09:56:47 7 you're breathing it in through --

09:56:47 8 THE COURT: So it's more like -- the way --  
09:56:51 9 maybe this is a bad analogy, but it's more like the things  
09:56:56 10 we're talking about. The centrifugal puncture, that's kind  
09:56:59 11 of like opening the package.

09:57:01 12 MR. JACKSON: Correct.

09:57:01 13 THE COURT: And then the delivery of the package  
09:57:03 14 is through breathing.

09:57:04 15 MR. JACKSON: Correct, Your Honor. So, again,  
09:57:07 16 referenced in the patent, and this is, in fact, the device  
09:57:10 17 that Liquidia's product uses.

09:57:14 18 Here's another figure in the patent. This is  
09:57:18 19 the one that you can see was used for the safety evaluation,  
09:57:23 20 the safety study. So that's our device, Figure 11. That is  
09:57:28 21 a breath-powered device, right.

09:57:30 22 So we have a picture of a breath-powered device  
09:57:33 23 in the patent itself. The force from that device does not  
09:57:36 24 come from the device itself. It comes from the patient  
09:57:38 25 breathing it in through that removable mouthpiece cover or

09:57:42 1 the white mouthpiece.

09:57:43 2 THE COURT: And I'm sorry to interrupt you with  
09:57:46 3 another random question. What's the priority date of this  
09:57:49 4 patent? I don't need the exact, but what year are we  
09:57:57 5 talking about; do you think?

09:57:58 6 MR. JACKSON: So I think it was -- the  
09:57:59 7 provisional was filed in 2020.

09:58:01 8 THE COURT: Okay. All right.

09:58:04 9 Sorry. Go ahead.

09:58:05 10 MR. JACKSON: So these are the three things  
09:58:08 11 referenced. These are the three dry powder inhalers.  
09:58:11 12 Again, we know dry powder inhalers are among pulsed  
09:58:14 13 inhalation devices.

09:58:15 14 These are the three dry powder inhalers  
09:58:17 15 referenced or pictured in the patent itself. Every one of  
09:58:22 16 them is breath-powered. Every one of them falls within the  
09:58:27 17 circle on the left, dry powder inhalers disclosed in the  
09:58:31 18 patent.

09:58:32 19 Liquidia's construction would require the dry  
09:58:35 20 powder inhalers to be powered by the device. Nothing, no  
09:58:39 21 dry powder inhalers are disclosed -- that are powered by the  
09:58:42 22 device are disclosed in the patent. That cannot be the  
09:58:46 23 right construction.

09:58:48 24 Liquidia instead focuses on nebulizers. And  
09:58:52 25 nebulizers are like blowing a mist to you. And there's lots

09:58:57 1 of nebulizers out there, including several that are  
09:58:59 2 referenced in the patent. And those can be, I don't  
09:59:02 3 necessarily think always are, but can be powered devices.  
09:59:06 4 So the force can come from the device.

09:59:09 5 And I'll agree that the force can come from the  
09:59:11 6 device. It just doesn't have to come from the device. It  
09:59:14 7 can also come from the person.

09:59:16 8 They focus -- they want the Court to focus on  
09:59:18 9 nebulizers which are powered not on dry powder inhaled  
09:59:23 10 devices. No dry powder inhalers fit Liquidia's definition.

09:59:30 11 THE COURT: And the reason why Claim 13 is not  
09:59:34 12 in the case is because the nebulizer is a mist and  
09:59:39 13 presumably their ANDA is claiming some kind of dry powder;  
09:59:42 14 right?

09:59:43 15 MR. JACKSON: Correct.

09:59:43 16 THE COURT: Okay.

09:59:44 17 MR. JACKSON: In fact, that's -- their dry  
09:59:46 18 powder is this dry powder. It is exactly this.

09:59:52 19 All right. So no -- none of their -- the dry  
09:59:58 20 powder inhalers is referenced in the patent or of which I'm  
10:00:00 21 aware fit their definition. In fact, when we asked in the  
10:00:04 22 preliminary injunction proceedings, asked their expert,  
10:00:05 23 using their definition: Have you ever encountered a pulsed  
10:00:10 24 inhalation device based on that the device has to supply the  
10:00:13 25 power that is also a dry powder inhaler? "No, not in my

10:00:16 1 experience."

10:00:16 2 So their expert isn't even aware of the  
10:00:19 3 existence of such a dry powder inhaler. So it may --

10:00:24 4 THE COURT: So just go back to that for a  
10:00:26 5 second. And yet the claim here is the pulsed inhalation  
10:00:34 6 device is a dry powder inhaler.

10:00:37 7 MR. JACKSON: Correct. He's using their  
10:00:38 8 definition of the device has to drive -- has to -- the force  
10:00:42 9 has to come from the device.

10:00:44 10 THE COURT: Oh, wait. Hold on.

10:00:46 11 So he's using their definition when he says it's  
10:00:55 12 a device that delivers a pulse?

10:00:57 13 MR. JACKSON: Correct.

10:00:57 14 THE COURT: But "delivers," wouldn't you use  
10:01:01 15 that terminology if you were breathing it in?

10:01:06 16 MR. JACKSON: So the thing I've highlighted in  
10:01:09 17 the three dots is about 12 lines long that elaborates, yes,  
10:01:14 18 I'm using the -- in essence, I'm using their definition. It  
10:01:17 19 would have been way too much to -- like I hate words on  
10:01:20 20 slides. I try to limit words on slides.

10:01:22 21 THE COURT: Well, we're in agreement on words on  
10:01:24 22 slides, but it's like you left out the trick in the Jack in  
10:01:29 23 the Box.

10:01:30 24 MR. JACKSON: Sorry.

10:01:32 25 THE COURT: All right. Well, go ahead.

10:01:33 1 MR. JACKSON: But so, again, this is what's  
10:01:35 2 disclosed in the patent. None of them fit in their  
10:01:38 3 construction. It just can't. The intrinsic evidence, you  
10:01:41 4 can't.

10:01:42 5 THE COURT: Okay. So I got these -- I got what  
10:01:44 6 you're saying about these three. I appreciate what you've  
10:01:46 7 said.

10:01:47 8 You had maybe other things you wanted to say?

10:01:50 9 MR. JACKSON: Yeah. So I've already -- it's --  
10:01:55 10 our definition is consistent with the specification. It's  
10:01:59 11 consistent with those three examples, and it distinguishes  
10:02:02 12 things, whether they are pulsed.

10:02:04 13 Their definition imports limits outside the  
10:02:08 14 specification. There's nothing in the specification about  
10:02:10 15 it being powered. Excludes embodiments in the  
10:02:13 16 specification. Includes those examples. Encompasses the  
10:02:16 17 device that Liquidia's expert admits doesn't exist. And  
10:02:19 18 focuses on nebulizers, not dry powder inhalers. And  
10:02:22 19 distinguishes based on whether they're powered not whether  
10:02:25 20 they're -- whether they are powered or not, not whether  
10:02:27 21 they're pulsed.

10:02:28 22 So this was the summary slide that kind of  
10:02:30 23 covered all the other pieces of --

10:02:32 24 THE COURT: Okay. You know, I didn't -- because  
10:02:34 25 there were too many words, I didn't read it all the first

10:02:37 1 time around. And there seemed like a lot of lines, but now  
10:02:40 2 I see the exemplary embodiments are taking up most of the  
10:02:43 3 space there, though it's consistent with the specification.  
10:02:47 4 I also saw that. And I get the last bullet point.

10:02:52 5 So unless you have something more, why don't I  
10:02:54 6 hear from your opponent. And, you know, this one I may  
10:03:02 7 easily -- I'll give you a chance to respond to whatever he  
10:03:06 8 says.

10:03:06 9 Okay?

10:03:07 10 MR. JACKSON: Thank you, Your Honor.

10:03:10 11 THE COURT: Are you Mr. -- is it Davies or  
10:03:13 12 Davis?

10:03:13 13 MR. DAVIES: Davies, Your Honor.

10:03:14 14 THE COURT: Davies, all right. Go ahead,  
10:03:18 15 Mr. Davies.

10:03:19 16 MR. DAVIES: Sorry. I think, as my friend  
10:03:39 17 indicated, the dispute between the parties is: Where does  
10:03:41 18 the pulse come from? And we think that our construction, in  
10:03:45 19 accordance with the plain and ordinary meaning, makes clear  
10:03:47 20 that the pulse is coming from the device, that it is a  
10:03:50 21 pulsed inhalation device. And that it's not, for example, a  
10:03:53 22 pulsed patient who's using an unpulsed device.

10:03:57 23 So our construction --

10:03:58 24 THE COURT: So --

10:03:59 25 MR. DAVIES: Yes.

10:04:00 1 THE COURT: -- one of the things that  
10:04:04 2 Mr. Jackson said, and I think maybe there was something in  
10:04:09 3 the briefing that indicates you think differently, but he  
10:04:13 4 says -- he didn't maybe specifically say this, but I  
10:04:16 5 understand his position to be that people of ordinary skill  
10:04:20 6 in the art understand pulsed is as opposed to continuous.

10:04:28 7 Do you agree with that?

10:04:29 8 MR. DAVIES: There is continuous, Your Honor.

10:04:30 9 We would classify those as respirators. They're also not a  
10:04:34 10 pulsed inhalation device because they're not pulsed in any  
10:04:38 11 way.

10:04:38 12 THE COURT: Right, right, right. I think he'd  
10:04:39 13 agree that they're not pulsed inhalation devices.

10:04:42 14 MR. SUKDUANG: Correct.

10:04:43 15 THE COURT: But in other words, it's the use of  
10:04:44 16 the word "pulsed" where, you know, my understanding of what  
10:04:51 17 Mr. Jackson said was, as opposed to, you know, what a layman  
10:04:57 18 might think is you have continuous and non-continuous. And  
10:05:00 19 those are opposites or at least different.

10:05:04 20 What he says is you have pulsed and you have  
10:05:07 21 non-continuous and they're different. Do you agree with  
10:05:10 22 that?

10:05:11 23 MR. DAVIES: I agree that there is a difference  
10:05:12 24 between pulsed and non-continuous. But within pulsed, you  
10:05:16 25 have those that are non-continuous and breath-powered. I'm

10:05:20 1 sorry. Within pulsed, you have to have force. So if it's a  
10:05:26 2 non-continuous device like a dry powder inhaler like what is  
10:05:29 3 used in Liquidia's product, that is breath-powered. So by  
10:05:33 4 adding in the force, we are distinguishing between the two  
10:05:36 5 types of inhalation devices that are non-continuous.

10:05:40 6 THE COURT: So how do you get around the  
10:05:42 7 references in the specification to the "pulsed inhalation  
10:05:50 8 devices" including things that appear to be non-pulsed  
10:05:53 9 according to your or -- you know, that involve no force  
10:05:58 10 according to -- how do you address that?

10:06:02 11 MR. DAVIES: So if you look at Slide 26, I  
10:06:04 12 think, of Mr. Jackson's presentation, he pointed to three  
10:06:07 13 pieces of evidence.

10:06:08 14 THE COURT: Yes.

10:06:09 15 MR. DAVIES: The first was *Guarneri* which is  
10:06:11 16 incorporated. If we -- and we will look at this. But when  
10:06:14 17 you look at how *Guarneri* is incorporated into the patent,  
10:06:17 18 it's incorporated for its disclosure of dry powder inhalers  
10:06:20 19 and powder compositions. It is not incorporated for its  
10:06:24 20 disclosure of pulsed inhalation device or pulsed dry powder  
10:06:28 21 inhalers.

10:06:28 22 The same for *Roscigno*. If you look at the spec,  
10:06:31 23 and we will look at the spec, how *Roscigno* is incorporated  
10:06:35 24 into the patent, it is incorporated for its references to  
10:06:37 25 inhalable composition. Again, it's not incorporated for an

10:06:41 1 example or an embodiment of a pulsed inhalation device or a  
10:06:45 2 pulsed dry powder inhaler.

10:06:46 3 And, lastly, Figure 11. Figure 11 is, again, an  
10:06:50 4 example of a dry powder inhaler. That is not a pulsed dry  
10:06:53 5 powder inhaler. It's just an example of a dry powder  
10:06:55 6 inhaler.

10:06:56 7 And as we've seen and as this Court has  
10:06:59 8 recognized, the spec discusses both inhalation devices and  
10:07:06 9 pulsed inhalation devices. The term "pulsed inhalation  
10:07:10 10 devices" only comes up as we've already discussed in the  
10:07:14 11 context of two dependent claims, 11 and 14. Claim 1 is not  
10:07:18 12 limited to a pulsed inhalation device.

10:07:21 13 THE COURT: So just not to nitpick, but why do  
10:07:28 14 you say limited to 11 and 14? Why isn't it also 12?

10:07:32 15 MR. DAVIES: To my knowledge, 11 and 14 are  
10:07:34 16 asserted. I'm not sure whether 12 is or not.

10:07:38 17 Okay. So 11, 12 and 14, Your Honor. I  
10:07:39 18 apologize.

10:07:40 19 THE COURT: No, it's all right.

10:07:41 20 MR. DAVIES: So going to this slide, as this  
10:07:44 21 Court recognized when it denied the PI motion, the patentees  
10:07:50 22 have not relied on any lexicography. And the spec only says  
10:07:54 23 that dry powder inhalers may be pulsed. It doesn't say that  
10:07:58 24 all are pulsed.

10:08:00 25 Therefore, UTC has this new argument where it

10:08:02 1 says it's not a lexicography argument anymore, it's an  
10:08:05 2 embodiment. And as I already described, and we'll walk  
10:08:08 3 through these portions of the spec, there are embodiments  
10:08:10 4 but those embodiments --

10:08:11 5 THE COURT: And I'm sorry --

10:08:12 6 MR. DAVIES: Yeah, yeah.

10:08:12 7 THE COURT: -- Mr. Davies. When you say it's a  
10:08:15 8 new argument because pulsed inhalation device is not defined  
10:08:20 9 in the specification, I reread my preliminary injunction  
10:08:26 10 opinion in the last 24 hours. Were they claiming it was  
10:08:30 11 lexicography at the preliminary injunction? Because I  
10:08:32 12 didn't see that in terms of --

10:08:34 13 MR. DAVIES: My understanding was they were  
10:08:36 14 saying that it was defined in that way, and that the  
10:08:38 15 argument during claim construction is now an embodiment  
10:08:40 16 argument rather than an indefiniteness argument.

10:08:42 17 THE COURT: No, I understand this is embodiment.  
10:08:43 18 But you're saying in the preliminary injunction stage, it  
10:08:46 19 was lexicography?

10:08:48 20 MR. DAVIES: I'm -- Your Honor, if I got that  
10:08:50 21 incorrect, I apologize.

10:08:51 22 THE COURT: I'm not -- I don't know. That's the  
10:08:53 23 reason why I'm trying to --

10:08:54 24 MR. DAVIES: My remembrance was that it was, but  
10:08:57 25 regardless, I think there's no disputing, given your

10:08:59 1 decision, there is no lexicography defining pulsed  
10:09:02 2 inhalation devices.

10:09:03 3 THE COURT: All right. That's fine. Go ahead.

10:09:05 4 MR. DAVIES: We already talked about the claim,  
10:09:07 5 so I'll skip over that.

10:09:09 6 Your Honor, the patent makes clear, again, that  
10:09:12 7 the -- and the spec is directed to inhalation devices and  
10:09:17 8 then only a subset of those are pulsed inhalation devices.  
10:09:21 9 And this is a portion of the spec that I don't believe we  
10:09:24 10 looked at with opposing counsel. But if you look at the  
10:09:27 11 language here, it says, "pulsed inhalation devices are  
10:09:30 12 disclosed." And then it describes -- it incorporates by  
10:09:34 13 reference a number of specifications there.

10:09:36 14 And if we look to the disclosure of those that  
10:09:39 15 are incorporated by reference specifically for, and I'll go  
10:09:43 16 back to it, specifically as examples of pulsed inhalation  
10:09:46 17 devices, all of these have examples of the Optineb-powered  
10:09:53 18 nebulizer which is what Plaintiff's product, Tyvaso, was  
10:09:56 19 approved for its use. So it's a powered device. It  
10:09:59 20 provides puffs of the drug that the patient then inhales.

10:10:02 21 It's undisputed, again, but the Optineb device  
10:10:06 22 is powered and that's how these pulses of drug are --

10:10:10 23 THE COURT: I'm sorry, Mr. Davies. Can you just  
10:10:11 24 go back?

10:10:12 25 MR. DAVIES: Yes.

10:10:12 1 THE COURT: Where in the spec -- one more slide  
10:10:14 2 back.

10:10:14 3 MR. DAVIES: Column 20.

10:10:16 4 THE COURT: This is 20.

10:10:17 5 MR. DAVIES: 44 to 57.

10:10:18 6 THE COURT: Please bear with me a minute.

10:10:20 7 Well, so that entire paragraph is littered with,  
10:11:01 8 for example, may be. It basically doesn't exclude anything;  
10:11:08 9 right?

10:11:08 10 MR. DAVIES: Well, I would -- and, Your Honor,  
10:11:10 11 maybe the best way to address this is let's look at the  
10:11:13 12 difference between this disclosure, which is Column 20,  
10:11:18 13 Lines 44 to 57 and then the disclosure that opposing counsel  
10:11:24 14 has relied on here for *Guarneri*.

10:11:25 15 Okay. So, again, if we look at Column 20, Lines  
10:11:29 16 44 to 57, it expressly says, when it's citing those things,  
10:11:33 17 pulsed inhalation devices are disclosed. Not nebulizers.  
10:11:37 18 Not dry powder inhalers. Pulsed inhalation devices are  
10:11:40 19 disclosed, and then it incorporates those.

10:11:42 20 If you look at the citation here to *Guarneri*, it  
10:11:46 21 doesn't say a pulsed dry powder inhaler is disclosed. It  
10:11:50 22 doesn't say a pulsed inhalation device is disclosed. It  
10:11:53 23 just says "a dry powder inhaler and a dry powder composition  
10:11:58 24 or formulation comprising treprostinil is disclosed."

10:12:01 25 And that's --

10:12:02 1 THE COURT: So --

10:12:02 2 MR. DAVIES: Mm-hmm.

10:12:03 3 THE COURT: -- looking at the sentence before  
10:12:05 4 that, it says, "In some embodiments the inhalation device,  
10:12:12 5 such as a pulsed inhalation device, may be a dry powder  
10:12:19 6 inhaler which may contain a dry powder composition" blah,  
10:12:23 7 blah, blah. "For example, a dry powder inhaler comprising  
10:12:30 8 treprostinil is disclosed in *Guarneri*."

10:12:33 9 Right?

10:12:34 10 MR. DAVIES: Correct, Your Honor. That's what  
10:12:35 11 it says.

10:12:36 12 THE COURT: Which is then incorporated herein by  
10:12:38 13 reference by its entirety. It kind of -- and I ask this  
10:12:46 14 against sort of the backdrop of, you know, the way I  
10:12:51 15 understand claim construction is that disclosing an example  
10:13:13 16 is, generally speaking, good, positive evidence that  
10:13:21 17 whatever the example is is included. Whereas, not  
10:13:26 18 disclosing the example is, generally speaking, not very good  
10:13:35 19 evidence that the example is not included and the sort of  
10:13:37 20 thing that leads to the Federal Circuit saying, Don't import  
10:13:42 21 the embodiments into the claims.

10:13:45 22 So if there's a sort of contest between their  
10:13:51 23 excerpt from page or Column 21, Line 6 to 14 and your's at  
10:13:59 24 Column 20, Lines 44 to 57, isn't theirs a lot more  
10:14:03 25 compelling?

10:14:04 1 MR. DAVIES: Your Honor, I'm not quite sure what  
10:14:06 2 you mean by the "contest." What I'm trying to draw a  
10:14:11 3 distinction between is the way in which they have  
10:14:13 4 incorporated these references. And we start from an  
10:14:15 5 understanding that the specification includes both general  
10:14:20 6 inhalation devices and then only a subset of those are  
10:14:23 7 pulsed. We don't disagree that you could have a pulsed  
10:14:26 8 inhalation device, but the examples and the embodiments in  
10:14:32 9 *Roscigno* are not identified as a pulsed dry powder inhaler.  
10:14:36 10 They're just identified as a dry powder inhaler that would  
10:14:38 11 fall in the general inhalation devices that would be covered  
10:14:41 12 by Claim 1 of this patent.

10:14:43 13 So it is an embodiment of the patent. It's just  
10:14:45 14 not an embodiment of a pulsed inhalation device which is  
10:14:48 15 only a subset of the inhalation devices that are described.

10:14:52 16 THE COURT: So the way I kind of read the flow  
10:14:53 17 of Column 21, Lines 6 to 14 is inhalation devices, general  
10:15:01 18 big category. Pulse inhalation devices, smaller big  
10:15:06 19 category. Dry powder inhalers, smaller category yet again.  
10:15:13 20 And then the dry powder inhalers include *Guarneri*, or  
10:15:19 21 *Roscigno* or whatever that is, which includes non-force dry  
10:15:25 22 powder inhalers.

10:15:25 23 So haven't they disclosed their pulsed  
10:15:34 24 inhalation device including the *Guarneri* or *Roscigno*,  
10:15:39 25 whichever, non-force device?

10:15:43 1 MR. DAVIES: I don't believe they have, Your  
10:15:45 2 Honor. And I believe the distinction between the two, the  
10:15:48 3 way they've done it in Column 20 where they have expressly  
10:15:51 4 incorporated by reference four pulsed inhalation devices is  
10:15:55 5 different than what they've done in 21. They didn't say  
10:15:59 6 another pulsed inhalation device is the *Roscigno* reference.  
10:16:03 7 A pulsed dry powder inhaler is the *Roscigno* reference. So I  
10:16:07 8 do read it differently, Your Honor.

10:16:09 9 And I think the way in which they're reading it  
10:16:11 10 goes against the plain and ordinary meaning that it's the  
10:16:14 11 device that has to be pulsed. So if you're going to go  
10:16:16 12 against that, to me you need -- you need a definition of  
10:16:19 13 that language to me is not clear and convincing enough to  
10:16:23 14 override the plain and ordinary meaning.

10:16:25 15 THE COURT: Well, so, okay. All right.

10:16:34 16 MR. DAVIES: Your Honor, this is the *Guarneri*  
10:16:36 17 reference, and we already looked at this. And, again,  
10:16:38 18 there's this distinction in *Guarneri* between dry powder  
10:16:41 19 inhalers that are disclosed in *Guarneri*, which it is relied  
10:16:45 20 on for versus the Optineb ultrasonic nebulizer, which is  
10:16:50 21 also disclosed in *Guarneri*, which the parties do not dispute  
10:16:52 22 is a pulsed device.

10:16:54 23 And, again, you have the contrast between the  
10:16:56 24 breath-powered inhaler, which, in our opinion, is simply a  
10:16:59 25 dry powder inhaler, which is simply an inhalation device as

10:17:02 1 of Claim 1 and not a pulsed inhalation device. So this  
10:17:08 2 reference in *Guarneri* is completely consistent with the way  
10:17:11 3 it's being relied on. The way it's being incorporated by  
10:17:14 4 the spec, it's being incorporated as a dry powder inhaler as  
10:17:17 5 a general inhalation device and not a pulsed inhalation  
10:17:20 6 device.

10:17:22 7 We don't rely on the definition, the dictionary  
10:17:29 8 definition for our term, but we believe it's consistent with  
10:17:32 9 our construction. It is the device that is providing the  
10:17:35 10 force. It is the device that is pulsed. It is not  
10:17:38 11 sufficient that the patient is pulsed through breathing.

10:17:42 12 It's also consistent with the declaration of  
10:17:45 13 Dr. Channick that was submitted in the PI briefing. And  
10:17:49 14 this is around Paragraphs 147 to 153. He said, "In my  
10:17:53 15 experience, pulsed inhalers are those where the device  
10:17:56 16 generates a force to expel drug from the device. Medication  
10:18:00 17 does not reach the patient through the force of the  
10:18:02 18 patient's breathing alone, but rather the device itself  
10:18:06 19 generates the same force."

10:18:07 20 So that's his understanding as a clinician in  
10:18:10 21 the pH space. And our position, Your Honor, is there's no  
10:18:13 22 definition in the patent. There is no definition in the  
10:18:15 23 patent that would contradict that plain and ordinary  
10:18:19 24 understanding.

10:18:20 25 Opposing counsel also pointed to *Roscigno* as an

10:18:27 1 example of a pulsed dry powder inhaler. But, again, if we  
10:18:30 2 look at how *Roscigno* is actually cited to and incorporated  
10:18:34 3 in the patent, it's relied on for its disclosure of  
10:18:38 4 inhalable compositions. "Inhalable compositions  
10:18:41 5 administered" may include any of those described in blah,  
10:18:45 6 blah, blah, blah. And then you get down to the *Roscigno*  
10:18:47 7 reference which is the PCT ending 993.

10:18:50 8 Again, it's not incorporated as a pulsed  
10:18:54 9 inhalation device. It's not incorporated as a pulsed dry  
10:18:58 10 powder inhaler. It's incorporated for its inhalable  
10:19:02 11 compositions, generally.

10:19:03 12 If we look at Figure 11 in the patent, again,  
10:19:10 13 Figure 11 does not refer to pulsed inhalation devices. So  
10:19:15 14 if we look at Paragraph 11, as with *Guarneri*, it has  
10:19:18 15 different disclosures for pulsed versus unpulsed. So  
10:19:23 16 Paragraph 11 refers to an ultrasonic pulsed nebulization  
10:19:27 17 delivery device.

10:19:28 18 And there's also Figure 11 that opposing counsel  
10:19:31 19 pointed you to, which is a dry powder inhaler, which we say  
10:19:34 20 is not pulsed. And, in fact, if you look at *Roscigno*, it's  
10:19:39 21 never referred to as a pulsed dry powder inhaler. It is a  
10:19:43 22 dry powder inhaler which is contrasted to the ultrasonic,  
10:19:46 23 pulsed nebulization delivery device.

10:19:50 24 And, Your Honor, this was also in the briefing,  
10:19:54 25 but the other big issue we have with opposing counsel's

10:20:00 1 construction is that under their construction it removes any  
10:20:03 2 distinction between pulsed and non-pulsed in the context of  
10:20:07 3 inhalation devices in that they equate a patient breathing  
10:20:11 4 with a pulse. And our position is if a patient breathing is  
10:20:15 5 enough to make it a pulsed inhalation device, then any  
10:20:18 6 inhalation device can be a pulsed inhalation device.

10:20:21 7 And the spec makes clear that they are two  
10:20:23 8 different categories. And, in fact, that pulsed inhalation  
10:20:26 9 devices are only a subset of the more general inhalation  
10:20:29 10 devices that are available.

10:20:30 11 Also, Dr. Nathan during his --

10:20:35 12 THE COURT: So --

10:20:36 13 MR. DAVIES: Yes.

10:20:36 14 THE COURT: -- what about what Mr. Jackson said  
10:20:40 15 about the patient with the -- you know, I forget what he  
10:20:45 16 called it, but, you know, somebody who's basically got like  
10:20:49 17 an oxygen machine. Can that be pulsed or non-pulsed?

10:21:00 18 MR. DAVIES: Under the Defendant's construction,  
10:21:03 19 I was expecting them to argue that that would be pulsed  
10:21:06 20 because the drug that enters the mouth is actually dependent  
10:21:09 21 on the patient breathing. If the patient has a breathing  
10:21:12 22 tube in, then it's continuous delivery.

10:21:15 23 So we don't see that as a meaningful  
10:21:17 24 distinction. It doesn't solve this problem that they've  
10:21:19 25 created with breath being sufficient for the pulse.

10:21:23 1 So our opinion, Your Honor, is the  
10:21:24 2 non-continuous part of the definition does not distinguish  
10:21:28 3 between the two classes that are disclosed in the patent.

10:21:31 4 THE COURT: Where do you get the non-continuous  
10:21:33 5 part from?

10:21:36 6 MR. DAVIES: The fact that it is pulsed, Your  
10:21:38 7 Honor, and then the pulse needs to come from the device.  
10:21:40 8 They allow for devices where the patient is pulsing.

10:21:44 9 THE COURT: So you agree with them that pulsed,  
10:21:51 10 at a minimum, means non-continuous?

10:21:53 11 MR. DAVIES: Yes, Your Honor. Yes.

10:21:55 12 THE COURT: Okay.

10:21:57 13 MR. DAVIES: We believe, though, that if you  
10:21:59 14 don't have the -- if you don't include the force  
10:22:01 15 requirement, that the force for that non-continuous delivery  
10:22:05 16 comes from the device, then it renders that distinction  
10:22:08 17 meaningless. The device itself, it is a pulsed inhalation  
10:22:13 18 device. It is not an inhalation device that is pulsed by a  
10:22:16 19 patient's breath.

10:22:18 20 So our plain and ordinary reading of that term  
10:22:20 21 is that the device itself has to be pulsed. The patient  
10:22:23 22 doesn't magically create an otherwise unpulsed device and  
10:22:27 23 make it pulsed.

10:22:29 24 THE COURT: Okay.

10:22:31 25 MR. DAVIES: So with that, Your Honor, it's our

10:22:36 1 position that pulsed inhalation device should be construed  
10:22:40 2 consistent with its plain and ordinary meaning. There is no  
10:22:42 3 definition in the spec that would contradict that. And, in  
10:22:45 4 fact, the disclosures that they rely on, the *Guarneri*,  
10:22:49 5 *Roscigno*, and Figure 11 of the '327 patent, none of them are  
10:22:52 6 incorporated for a disclosure of a pulsed inhalation device  
10:22:56 7 or a pulsed dry powder inhaler.

10:22:58 8 THE COURT: Do you think the term "inhalation  
10:23:04 9 devices," does that only refer to devices that are -- well,  
10:23:14 10 so I remember when my children were young and they used to  
10:23:17 11 have diseases of one kind or another, we had a device that,  
10:23:23 12 for lack of a better word, misted up the room with -- I  
10:23:28 13 don't know. I think it probably had a lot of water in it to  
10:23:30 14 help breathing or something like that.

10:23:32 15 Is that an inhalation device?

10:23:33 16 MR. DAVIES: That could be an inhalation device,  
10:23:36 17 Your Honor. I don't know expressly which one you're  
10:23:39 18 referring to, but I --

10:23:40 19 THE COURT: It's been a long time. And would  
10:23:47 20 you say that was a pulsed inhalation device?

10:23:49 21 MR. DAVIES: It would depend on what the  
10:23:51 22 delivery was. If the force was provided by the machine and  
10:23:55 23 delivered in pulses to the patient, it was non-continuous.

10:23:58 24 THE COURT: Well, so imagine a child's bedroom,  
10:24:02 25 and this is like in the corner of the bedroom kind of

10:24:05 1 blowing water vapor out into the air. The child's just  
10:24:09 2 breathing on his or her own. Is that a pulsed inhalation  
10:24:14 3 device?

10:24:15 4 MR. DAVIES: If the delivery is continuous, then  
10:24:18 5 no, it is not because we believe it also has to be  
10:24:21 6 non-continuous.

10:24:23 7 THE COURT: Okay. Anything else?

10:24:25 8 MR. DAVIES: No.

10:24:26 9 THE COURT: All right. Thank you.

10:24:28 10 MR. DAVIES: Thank you, Your Honor.

10:24:29 11 THE COURT: Mr. Jackson.

10:24:31 12 MR. JACKSON: I'm just going to come back to  
10:24:37 13 this slide. I think you understand where I'm coming from,  
10:24:40 14 and I don't want to waste the Court's time, unless the Court  
10:24:43 15 has questions.

10:24:43 16 I think the basic difference is our view is  
10:24:46 17 pulsed inhalation devices, there are two categories. Either  
10:24:49 18 it's pulsed inhalation or continuous inhalation. And pulsed  
10:24:54 19 inhalation just means it delivers a bolus. It delivers a  
10:24:58 20 pulse.

10:24:59 21 And so a pulse gets delivered to -- if it's  
10:25:03 22 through inhalation, right. It is the inhalation that is  
10:25:07 23 pulsed by breathing it in or by the machine delivering it.  
10:25:15 24 It's where it's -- but the force does not have to come from  
10:25:18 25 the device itself, as we said in the spec or as we -- the

10:25:21 1 example we showed in the spec.

10:25:23 2 So unless the Court has questions.

10:25:27 3 THE COURT: Well, so I'm trying to recall.

10:25:34 4 Mr. Davies said, and I think it was in the briefing, too,  
10:25:40 5 that your -- so I think they said your definition is too  
10:25:53 6 broad because it erases the distinction between -- I think  
10:26:07 7 between pulsed inhalation and just inhalation. But I take  
10:26:13 8 it what you'd say is, no, you know, pulsed inhalation  
10:26:29 9 includes any non-continuous device. If you want to break it  
10:26:32 10 down to nebulizers, or dry powder inhalers or something  
10:26:37 11 else, that's a further way you can break it down. But the  
10:26:41 12 category of pulse inhalation devices is broad enough to  
10:26:45 13 include all of those things.

10:26:47 14 MR. JACKSON: Correct. And with all due respect  
10:26:49 15 to Mr. Davies, his characterization of my argument of our  
10:26:54 16 stance is a strawman that they set up in order to knock  
10:26:57 17 down. We were -- we've been clear that the pulsed  
10:27:00 18 inhalation device is a -- it needs to deliver a pulse of the  
10:27:04 19 given medicine or the given -- whatever it's delivering in a  
10:27:08 20 pulse, right. It just can't be continuous.

10:27:10 21 That's why I said the cannula, the thing over  
10:27:12 22 your nose, and it's constant oxygen. That's continuous, not  
10:27:15 23 pulsed. So it's -- the only question -- the only debate  
10:27:20 24 between the parties here is: Where does the force for that  
10:27:22 25 thing have to come from? Where does the force for the pulse

10:27:25 1 that you're inhaling have to come from? Does it come only  
10:27:28 2 from the device or can it come from the human? The examples  
10:27:31 3 in the specification show it can come from the human by when  
10:27:34 4 you breathe in.

10:27:35 5 THE COURT: Okay. Thank you.

10:27:37 6 MR. JACKSON: Thank you, Your Honor.

10:27:37 7 THE COURT: Do you have anything more,  
10:27:40 8 Mr. Davies?

10:27:42 9 MR. DAVIES: The last thing I'll say, Your  
10:28:03 10 Honor, is under their or at least our understanding of their  
10:28:07 11 construction, there's no difference between a general DPI or  
10:28:12 12 a DPI that's pulsed.

10:28:14 13 THE COURT: I'm sorry.

10:28:14 14 MR. DAVIES: A general dry powder inhaler.  
10:28:14 15 Sorry.

10:28:14 16 THE COURT: Thank you.

10:28:19 17 MR. DAVIES: Under their construction, there  
10:28:20 18 would be no difference between a dry powder inhaler and a  
10:28:22 19 pulsed dry powder inhaler because they and their expert are  
10:28:28 20 equating breaths with the pulse. So there's no distinction  
10:28:30 21 between dry powder inhalers for those that would be pulsed  
10:28:34 22 versus those that would not be pulsed under their  
10:28:36 23 construction.

10:28:37 24 Our construction --

10:28:38 25 THE COURT: Yeah, but nobody's claiming a pulsed

10:28:40 1 dry powder inhaler, so why does that matter?

10:28:44 2 MR. DAVIES: Well, they are, Your Honor. They  
10:28:45 3 are in Claim 14. It's the -- where the -- a claim -- method  
10:28:59 4 of claim 11 where the pulsed inhalation device is a dry  
10:29:02 5 powder inhaler.

10:29:02 6 THE COURT: No, but the way you were saying it,  
10:29:04 7 what I meant is there's no claim that says the -- that has  
10:29:15 8 the sort of phrase "pulsed dry powder inhaler" as opposed to  
10:29:20 9 non-pulsed dry powder inhaler. So saying you can't tell the  
10:29:28 10 difference between the two doesn't matter because nobody's  
10:29:30 11 trying to tell the difference between the two.

10:29:32 12 MR. DAVIES: Well, as we looked at in the spec,  
10:29:33 13 the spec refers to dry powder inhalers with no reference to  
10:29:38 14 pulsed dry powder inhalers. Claim 1 is broader and does not  
10:29:41 15 contain this limitation for pulsed inhalers. So in our  
10:29:46 16 mind, there is a distinction that's important, Your Honor.

10:29:48 17 THE COURT: Okay. All right.

10:29:49 18 So let me just take a very short break here.  
10:29:53 19 Don't go anywhere. We'll be right back.

10:29:55 20 (Recess was taken.)

10:34:12 21 THE CLERK: All rise.

10:34:23 22 THE COURT: Have a seat. So I have a question  
10:34:28 23 which may or may not have something to do with what we're  
10:34:32 24 actually doing here, but it is: With the dry powder  
10:34:41 25 inhaler, is there basically a cartridge that has one dose?

10:34:48 1 You put the cartridge in. You inhale it. Then if you want  
10:34:52 2 another one, you have to put another cartridge in and inhale  
10:34:55 3 it.

10:34:56 4 And, you know, is that basically what we're  
10:34:59 5 talking about?

10:35:00 6 MR. JACKSON: That's my understanding of -- for  
10:35:04 7 example, our device that's in Figure 11 in the patent and  
10:35:08 8 the device in *Roscigno*, I need to double-check before I  
10:35:11 9 answer on *Guarneri*, but I believe that's the case in  
10:35:14 10 *Guarneri* as well.

10:35:14 11 THE COURT: All right. Thank you.

10:35:15 12 MR. JACKSON: So, yes.

10:35:16 13 MR. DAVIES: For our device, it's -- Your Honor,  
10:35:18 14 the dose is contained in a pill. You put that in. It's  
10:35:21 15 punctured. And then it's the breath of the patient that  
10:35:24 16 spins the pill and draws the -- pulls it out, provides the  
10:35:28 17 force.

10:35:28 18 THE COURT: But is it one breath of the patient?

10:35:31 19 MR. DAVIES: Three.

10:35:33 20 MR. SUKDUANG: Up to three.

10:35:34 21 MR. DAVIES: Up to three.

10:35:34 22 THE COURT: Okay. And you say "up to three." I  
10:35:38 23 mean, are the instructions do it three times?

10:35:41 24 MR. DAVIES: Three times, yes.

10:35:43 25 THE COURT: Okay.

10:35:46 1 MR. SUKDUANG: I'm sorry. One clarification,  
10:35:48 2 and similar to their device, each capsule has one dose.

10:35:53 3 THE COURT: Right.

10:35:53 4 MR. SUKDUANG: It may take three breaths to get  
10:35:56 5 the entire dose. But as you increase, you might need to  
10:35:59 6 take two capsules. So you put one capsule in, breathe up to  
10:36:02 7 three times. Take the capsule out, put another capsule in.  
10:36:06 8 Breathe up to three times, take the capsule out. So the two  
10:36:09 9 capsules combined might constitute one dose.

10:36:12 10 THE COURT: Okay. But the point of between  
10:36:17 11 continuous and non-continuous is that unlike, say, the thing  
10:36:24 12 where it's attached to your nose is you take the one dose  
10:36:30 13 and then time passes before you take another dose; right,  
10:36:34 14 even if you're doing two cartridges?

10:36:38 15 MR. JACKSON: Well, there are times when you can  
10:36:39 16 have that cannula behind your nose. The constant oxygen,  
10:36:42 17 for example. That's constant. That's continuous.

10:36:45 18 THE COURT: Right, right. But talking about  
10:36:50 19 treprostinil that what makes it non-continuous is you do  
10:36:53 20 your one dose, which may be one cartridge, may be two  
10:36:57 21 cartridges, may be six breaths. But that's one dose. And  
10:37:02 22 you've done that, and then you don't do it again for some  
10:37:06 23 period of time that's probably hours at least and perhaps  
10:37:12 24 24 hours, but some period of time; right?

10:37:14 25 MR. JACKSON: Yes, Your Honor.

10:37:15 1 THE COURT: Right?

10:37:15 2 MR. DAVIES: Correct, Your Honor. Yes.

10:37:17 3 THE COURT: Okay. All right.

10:37:19 4 Well, I think I know what I am probably going to  
10:37:21 5 do about non-continuous "pulsed inhalation device," but I  
10:37:29 6 think it's worthwhile putting it in writing. So I'm going  
10:37:33 7 to take that under advisement, and we'll get you something  
10:37:41 8 before too long.

10:37:42 9 When is the next scheduled event in this case  
10:37:45 10 that involves me?

10:37:47 11 MR. SUKDUANG: Pretrial, we believe, Your Honor.

10:37:49 12 THE COURT: And when's that?

10:37:51 13 MR. SUKDUANG: I believe trial is  
10:37:53 14 September 2025. Oh, I have the schedule. Yeah. So we have  
10:37:57 15 the pretrial June 3, '25.

10:37:59 16 THE COURT: Okay.

10:38:00 17 MR. SUKDUANG: And trial June 23, '25.

10:38:04 18 THE COURT: Oh.

10:38:05 19 MR. SUKDUANG: And depending on whether Liquidia  
10:38:12 20 gets to launch in May or not, that could change this,  
10:38:16 21 depending on the parties' decision. It could change from a  
10:38:20 22 bench to a jury if UTC ends up seeking monetary damages.  
10:38:26 23 And then in that instance, if it switches to a jury,  
10:38:31 24 Liquidia may seek or they may seek the right to file summary  
10:38:36 25 judgment. Because as of right now, it is planned as a bench

10:38:40 1 trial, so there's no summary judgment.

10:38:42 2 So things could change depending on whether we  
10:38:44 3 launch or not and whether damages are sought.

10:38:49 4 THE COURT: All right.

10:38:49 5 MR. SUKDUANG: But that's where we sit.

10:38:51 6 THE COURT: All right. I take it the Plaintiff  
10:38:56 7 asked for a jury trial or somebody's asked for a jury trial  
10:39:00 8 here?

10:39:01 9 MR. SUKDUANG: Not initially because there was  
10:39:02 10 no damages. We weren't on the market when the case was  
10:39:04 11 filed.

10:39:05 12 THE COURT: No, no. I understand that. So you  
10:39:06 13 can get a jury trial even though you didn't ask for it at  
10:39:09 14 the beginning?

10:39:10 15 MR. SUKDUANG: We may ask. The situation  
10:39:12 16 changed. So we may not ask for a jury trial. But if  
10:39:15 17 they're asking for monetary damages, we don't know if  
10:39:17 18 they're going to ask for a jury trial.

10:39:19 19 THE COURT: Okay. Mr. Jackson.

10:39:21 20 MR. JACKSON: Yeah. I -- yes. We -- to the  
10:39:25 21 degree they launch, we would seek a jury trial. And yes --

10:39:28 22 THE COURT: And did you ask for that in the  
10:39:30 23 Complaint?

10:39:31 24 MR. JACKSON: I don't believe so because I think  
10:39:34 25 at that point it was just a -- it was -- we didn't have a

10:39:37 1 right to it because there was no -- it was just, in essence,  
10:39:41 2 a Hatch-Waxman.

10:39:42 3 THE COURT: Okay. All right.

10:39:44 4 MR. JACKSON: Can I just do one other  
10:39:45 5 housekeeping thing?

10:39:47 6 THE COURT: Sure.

10:39:47 7 MR. JACKSON: You asked me earlier which claims  
10:39:50 8 we're asserting, and I said all -- 11 through 14 for the  
10:39:54 9 relevant claim. It turns out -- we agreed not 13 because  
10:39:57 10 that was the nebulizer.

10:39:58 11 It turns out not 12. I went back, and  
10:40:02 12 Mr. Sukduang and I conferred. And he's -- we are not  
10:40:05 13 asserting 12. So it's just 11 and 14 for the purposes of  
10:40:08 14 the "pulsed inhalation device" definition.

10:40:11 15 THE COURT: And but all the rest of the  
10:40:13 16 claims -- so other than 12 and 13, you're still asserting  
10:40:16 17 all the claims in the patent?

10:40:17 18 MR. JACKSON: I believe that's right. Yes.

10:40:19 19 THE COURT: Okay.

10:40:20 20 MR. JACKSON: Thank you, Your Honor.

10:40:20 21 THE COURT: Thank you for that. All right.

10:40:22 22 Well, like I said, I'll take it under advisement  
10:40:24 23 and see you later.

10:40:26 24 ALL COUNSEL: Thank you, Your Honor.

10:40:30 25 (Court was recessed.)

1 I hereby certify the foregoing is a true and  
2 accurate transcript from my stenographic notes in the  
3 proceeding.

4 /s/ Heather M. Triozzi  
5 Certified Merit and Real-Time Reporter  
U.S. District Court

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